Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Sacituzumab govitecan (Trodelvy®)

Gilead Sciences GmbH

Anhang 4-G

Monotherapie zur Behandlung von erwachsenen Patienten mit nicht resezierbarem oder metastasiertem Hormonrezeptor (HR)-positivem, HER2-negativem Mammakarzinom, die eine Endokrin-basierte Therapie und mindestens zwei zusätzliche systemische Therapien bei fortgeschrittener Erkrankung erhalten haben

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 14.08.2023

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Study IMMU-132-09

Table 15.1.1.1: participant Disposition
Screened Population
Excluding Participants Pre-selected to Gemcitabine

	SG n (%)	TPC n (%)	Total n (%)
Subjects Screened			651
Subjects Randomized (ITT Population)	205	213	418
Subjects Randomized but not Treated	4 (2.0%)	19 (8.9%)	23 (5.5%)
Received at Least One Dose of Study Treatment (Safety Population)	201 (98.0%)	194 (91.1%)	395 (94.5%)
Treatment Status			
Continuing on Treatment	7 (3.4%)	2 (0.9%)	9 (2.2%)
Discontinued from Study Treatment	194 (94.6%)	192 (90.1%)	386 (92.3%)
Primary Reason for Discontinuing Treatment			
Progressive Disease	162 (79.0%)	160 (75.1%)	322 (77.0%)
Clinical Progression	13 (6.3%)	11 (5.2%)	24 (5.7%)
Radiological Progression	149 (72.7%)	149 (70.0%)	298 (71.3%)
Protocol Deviation (Non-Compliance)	1 (0.5%)	3 (1.4%)	4 (1.0%)
Death	2 (1.0%)	2 (0.9%)	4 (1.0%)
Treatment Delay > 3 Weeks	3 (1.5%)	1 (0.5%)	4 (1.0%)
Withdrawal of Consent	8 (3.9%)	14 (6.6%)	22 (5.3%)
Treatment Only	6 (2.9%)	7 (3.3%)	13 (3.1%)
Survival Follow-up	2 (1.0%)	7 (3.3%)	9 (2.2%)
Adverse Event	14 (6.8%)	6 (2.8%)	20 (4.8%)
Pregnancy	0	0	0
Lost to Follow-Up	0	0	0
Covid-19	0	1 (0.5%)	1 (0.2%)
Study Drug Not Administered (After Randomization)	0	0	0
Other	4 (2.0%)	5 (2.3%)	9 (2.2%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.

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Table 15.1.1.1: participant Disposition
Screened Population
Excluding Participants Pre-selected to Gemcitabine

	SG n (%)	TPC n (%)	Total n (%)
Number of Subjects Continuing on Study	54 (26.3%)	47 (22.1%)	101 (24.2%)
Number of Subjects who Discontinued from Study	151 (73.7%)	166 (77.9%)	317 (75.8%)
Primary Reason for Discontinuing from Study			
Death	136 (66.3%)	119 (55.9%)	255 (61.0%)
Withdrawal of Consent	8 (3.9%)	33 (15.5%)	41 (9.8%)
Lost to Follow-Up	3 (1.5%)	6 (2.8%)	9 (2.2%)
Sponsor Decision	0	1 (0.5%)	1 (0.2%)
Covid-19	0	1 (0.5%)	1 (0.2%)
Other	4 (2.0%)	6 (2.8%)	10 (2.4%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.

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Table 15.1.1.1.2: Participant Disposition at Final OS Data
Screened Population
Excluding Participants Pre-selected to Gemcitabine

	SG n (%)	TPC n (%)	Total n (%)
Subjects Screened			651
Subjects Randomized (ITT Population)	205	213	418
Subjects Randomized but not Treated	4 (2.0%)	19 (8.9%)	23 (5.5%)
Received at Least One Dose of Study Treatment (Safety Population)	201 (98.0%)	194 (91.1%)	395 (94.5%)
Treatment Status			
Continuing on Treatment	5 (2.4%)	1 (0.5%)	6 (1.4%)
Discontinued from Study Treatment	196 (95.6%)	193 (90.6%)	389 (93.1%)
Primary Reason for Discontinuing Treatment			
Progressive Disease	164 (80.0%)	161 (75.6%)	325 (77.8%)
Clinical Progression	13 (6.3%)	11 (5.2%)	24 (5.7%)
Radiological Progression	151 (73.7%)	150 (70.4%)	301 (72.0%)
Protocol Deviation (Non-Compliance)	1 (0.5%)	3 (1.4%)	4 (1.0%)
Death	2 (1.0%)	2 (0.9%)	4 (1.0%)
Treatment Delay > 3 Weeks	3 (1.5%)	1 (0.5%)	4 (1.0%)
Withdrawal of Consent	8 (3.9%)	14 (6.6%)	22 (5.3%)
Treatment Only	6 (2.9%)	7 (3.3%)	13 (3.1%)
Survival Follow-up	2 (1.0%)	7 (3.3%)	9 (2.2%)
Adverse Event	14 (6.8%)	6 (2.8%)	20 (4.8%)
Pregnancy	0	0	0
Lost to Follow-Up	0	0	0
Covid-19	0	1 (0.5%)	1 (0.2%)
Study Drug Not Administered (After Randomization)	0	0	0
Other	4 (2.0%)	5 (2.3%)	9 (2.2%)

The denominator is the number of patients in the ITT Population excluding those assigned to Gemcitabine before randomized for each treatment group.
Final OS data cut is at 01Dec2022.

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Table 15.1.1.1.2: Participant Disposition at Final OS Data
Screened Population
Excluding Participants Pre-selected to Gemcitabine

	SG n (%)	TPC n (%)	Total n (%)
Number of Subjects Continuing on Study	36 (17.6%)	28 (13.1%)	64 (15.3%)
Number of Subjects who Discontinued from Study	169 (82.4%)	185 (86.9%)	354 (84.7%)
Primary Reason for Discontinuing from Study			
Death	154 (75.1%)	138 (64.8%)	292 (69.9%)
Withdrawal of Consent	9 (4.4%)	33 (15.5%)	42 (10.0%)
Lost to Follow-Up	2 (1.0%)	6 (2.8%)	8 (1.9%)
Sponsor Decision	0	1 (0.5%)	1 (0.2%)
Covid-19	0	1 (0.5%)	1 (0.2%)
Other	4 (2.0%)	6 (2.8%)	10 (2.4%)

The denominator is the number of patients in the ITT Population excluding those assigned to Gemcitabine before randomized for each treatment group.
Final OS data cut is at 01Dec2022.

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Table 15.1.1.2: participant Disposition
Screened Population
Only including participants never dosed but excluding participants pre-selected to Gemcitabine

	SG n (%)	TPC n (%)	Total n (%)
Subjects Screened			256
Subjects Randomized but not Treated	4 (100.0%)	19 (100.0%)	23 (100.0%)
Number of Subjects who Discontinued from Study	4 (100.0%)	19 (100.0%)	23 (100.0%)
Primary Reason for Discontinuing from Study			
Withdrawal of Consent	1 (25.0%)	12 (63.2%)	13 (56.5%)
Sponsor Decision	0	1 (5.3%)	1 (4.3%)
Other	3 (75.0%)	6 (31.6%)	9 (39.1%)

The denominator is the number of patients in the ITT Population but never dosed excluding participants assigned to Gemcitabine before randomized for each treatment group.

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Table 15.1.1.2.2: Participant Disposition at Final OS Data
Screened Population
Only including participants never dosed but excluding participants pre-selected to Gemcitabine

	SG n (%)	TPC n (%)	Total n (%)
Subjects Screened			256
Subjects Randomized but not Treated	4 (100.0%)	19 (100.0%)	23 (100.0%)
Number of Subjects who Discontinued from Study	4 (100.0%)	19 (100.0%)	23 (100.0%)
Primary Reason for Discontinuing from Study			
Withdrawal of Consent	1 (25.0%)	12 (63.2%)	13 (56.5%)
Sponsor Decision	0	1 (5.3%)	1 (4.3%)
Other	3 (75.0%)	6 (31.6%)	9 (39.1%)

The denominator is the number of patients in the ITT Population but never dosed excluding participants assigned to Gemcitabine before randomized for each treatment group.
Final OS data cut is at 01Dec2022.

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Table 15.1.3.1: Demographics and Baseline Characteristics
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Age at Study Entry (years)			
N	205	213	418
Mean (SD)	56.3 (10.99)	55.4 (10.34)	55.9 (10.66)
Median	56.0	55.0	55.0
Minimum	29	27	27
Maximum	86	78	86
Age Group, n (%)			
< 65 years	158 (77.1%)	161 (75.6%)	319 (76.3%)
>= 65 years	47 (22.9%)	52 (24.4%)	99 (23.7%)
< 50 years	55 (26.8%)	63 (29.6%)	118 (28.2%)
>= 50 and <65 years	103 (50.2%)	98 (46.0%)	201 (48.1%)
>= 65 years	47 (22.9%)	52 (24.4%)	99 (23.7%)
Sex, n (%)			
Male	2 (1.0%)	3 (1.4%)	5 (1.2%)
Female	203 (99.0%)	210 (98.6%)	413 (98.8%)
If Female, Childbearing Potential, n (%)			
N	203	210	413
Yes	23 (11.3%)	25 (11.9%)	48 (11.6%)
No	180 (88.7%)	183 (87.1%)	363 (87.9%)
Missing	0	2 (1.0%)	2 (0.5%)

[a] Not reported indicates local regulators did not allow collection of race or ethnicity information.
[b] BMI is calculated as BMI (kg/m^2) = (weight in kg) / (height in m)^2. [c] Based on Du Bois formula 0.007184 x weight(kg)^0.425 x height(cm)^0.725.
[d] Creatinine clearance is derived by using Cockcroft-Gault Equation, which may deviate from the value collected by the site at screening.
[e] Normal: Bilirubin (BILI) <= ULN and Aspartate transaminase (AST) <= ULN; Mild Hepatic Impairment (HI): 1) BILI <= ULN and AST > ULN or 2) ULN < BILI <= 1.5x ULN; Moderate HI: 1.5x ULN < BILI <= 3x ULN; Severe HI: BILI > 3x ULN.
[f] Collected only if required per local guidelines for participants receiving capecitabine.
[g] Baseline UGT1A1 includes 2 participants with samples after C1D1 (7 and 49 days after C1D1 respectively); Other includes *1|*36, *1|*37 and

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Table 15.1.3.1: Demographics and Baseline Characteristics
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Race, n (%)			
American Indian or Alaska Native	0	0	0
Asian	7 (3.4%)	5 (2.3%)	12 (2.9%)
Black or African American	7 (3.4%)	8 (3.8%)	15 (3.6%)
Multiple	0	1 (0.5%)	1 (0.2%)
Native Hawaiian or Other Pacific Islander	0	1 (0.5%)	1 (0.2%)
White	143 (69.8%)	143 (67.1%)	286 (68.4%)
Other	0	3 (1.4%)	3 (0.7%)
Not Reported [a]	48 (23.4%)	52 (24.4%)	100 (23.9%)
Ethnicity, n (%)			
Hispanic or Latino	4 (2.0%)	10 (4.7%)	14 (3.3%)
Not Hispanic or Latino	169 (82.4%)	161 (75.6%)	330 (78.9%)
Unknown	12 (5.9%)	8 (3.8%)	20 (4.8%)
Not Reported [a]	19 (9.3%)	27 (12.7%)	46 (11.0%)
Missing	1 (0.5%)	7 (3.3%)	8 (1.9%)
Region, n (%)			
North America	80 (39.0%)	83 (39.0%)	163 (39.0%)
Europe	125 (61.0%)	130 (61.0%)	255 (61.0%)

[a] Not reported indicates local regulators did not allow collection of race or ethnicity information.
[b] BMI is calculated as BMI (kg/m^2) = (weight in kg) / (height in m)^2. [c] Based on Du Bois formula 0.007184 x weight(kg)^0.425 x height(cm)^0.725.
[d] Creatinine clearance is derived by using Cockcroft-Gault Equation, which may deviate from the value collected by the site at screening.
[e] Normal: Bilirubin (BILI) <= ULN and Aspartate transaminase (AST) <= ULN; Mild Hepatic Impairment (HI): 1) BILI <= ULN and AST > ULN or
2) ULN < BILI <= 1.5x ULN; Moderate HI: 1.5x ULN < BILI <= 3x ULN; Severe HI: BILI > 3x ULN.
[f] Collected only if required per local guidelines for participants receiving capecitabine.
[g] Baseline UGT1A1 includes 2 participants with samples after C1D1 (7 and 49 days after C1D1 respectively); Other includes *1|*36, *1|*37 and

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Table 15.1.3.1: Demographics and Baseline Characteristics
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Baseline Weight (kg)			
N	203	212	415
Mean (SD)	69.0 (15.80)	67.1 (15.07)	68.0 (15.44)
Median	67.0	63.8	65.6
Minimum	40.1	35.6	35.6
Maximum	160.1	125.9	160.1
Baseline Height (cm)			
N	194	199	393
Mean (SD)	163.8 (6.91)	163.2 (6.82)	163.5 (6.86)
Median	163.3	163.0	163.0
Minimum	144.8	145.5	144.8
Maximum	185.0	180.3	185.0
Baseline Body Mass Index (BMI) (kg/m2) [b]			
N	194	199	393
Mean (SD)	25.8 (5.79)	25.2 (5.33)	25.5 (5.56)
Median	25.0	24.2	24.6
Minimum	16.3	15.8	15.8
Maximum	61.0	44.8	61.0

[a] Not reported indicates local regulators did not allow collection of race or ethnicity information.
[b] BMI is calculated as BMI (kg/m^2) = (weight in kg) / (height in m)^2. [c] Based on Du Bois formula 0.007184 x weight(kg)^0.425 x height(cm)^0.725.
[d] Creatinine clearance is derived by using Cockcroft-Gault Equation, which may deviate from the value collected by the site at screening.
[e] Normal: Bilirubin (BILI) <= ULN and Aspartate transaminase (AST) <= ULN; Mild Hepatic Impairment (HI): 1) BILI <= ULN and AST > ULN or
2) ULN < BILI <= 1.5x ULN; Moderate HI: 1.5x ULN < BILI <= 3x ULN; Severe HI: BILI > 3x ULN.
[f] Collected only if required per local guidelines for participants receiving capecitabine.
[g] Baseline UGT1A1 includes 2 participants with samples after C1D1 (7 and 49 days after C1D1 respectively); Other includes *1|*36, *1|*37 and

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Table 15.1.3.1: Demographics and Baseline Characteristics
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Baseline Body Surface Area (m2) [c]			
N	194	199	393
Mean (SD)	1.7 (0.18)	1.7 (0.19)	1.7 (0.18)
Median	1.7	1.7	1.7
Minimum	1.4	1.2	1.2
Maximum	2.5	2.3	2.5
Baseline Creatinine Clearance (Cockcroft-Gault Equation; mL/min)[d]			
N	203	213	416
Mean (SD)	97.6 (34.11)	99.7 (34.53)	98.7 (34.30)
Median	92.9	94.9	93.4
Minimum	31.7	31.5	31.5
Maximum	282.1	263.1	282.1
Baseline Renal Function, n (%)[d]			
Creatinine clearance < 30 mL/min	0	0	0
30 mL/min <= Creatinine clearance < 60 mL/min	15 (7.3%)	17 (8.0%)	32 (7.7%)
60 mL/min <= Creatinine clearance < 90 mL/min	78 (38.0%)	77 (36.2%)	155 (37.1%)
Creatinine clearance >= 90 mL/min	110 (53.7%)	119 (55.9%)	229 (54.8%)
Missing	2 (1.0%)	0	2 (0.5%)

[a] Not reported indicates local regulators did not allow collection of race or ethnicity information.
[b] BMI is calculated as BMI (kg/m^2) = (weight in kg) / (height in m)^2. [c] Based on Du Bois formula 0.007184 x weight(kg)^0.425 x height(cm)^0.725.
[d] Creatinine clearance is derived by using Cockcroft-Gault Equation, which may deviate from the value collected by the site at screening.
[e] Normal: Bilirubin (BILI) <= ULN and Aspartate transaminase (AST) <= ULN; Mild Hepatic Impairment (HI): 1) BILI <= ULN and AST > ULN or 2) ULN < BILI <= 1.5x ULN; Moderate HI: 1.5x ULN < BILI <= 3x ULN; Severe HI: BILI > 3x ULN.
[f] Collected only if required per local guidelines for participants receiving capecitabine.
[g] Baseline UGT1A1 includes 2 participants with samples after C1D1 (7 and 49 days after C1D1 respectively); Other includes *1|*36, *1|*37 and

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Table 15.1.3.1: Demographics and Baseline Characteristics
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Baseline Hepatic Function, n (%)[e]			
Normal	88 (42.9%)	83 (39.0%)	171 (40.9%)
Mild	113 (55.1%)	126 (59.2%)	239 (57.2%)
Moderate	2 (1.0%)	4 (1.9%)	6 (1.4%)
Severe	0	0	0
Missing	2 (1.0%)	0	2 (0.5%)
Baseline Blood Uracil Level (ng/mL) [f]			
N		8	8
Mean (SD)		5758.0 (16260.23)	5758.0 (16260.23)
Median		9.3	9.3
Minimum		6.5	6.5
Maximum		46000.0	46000.0
UGT1A1 Genotype (SG only), n (%)[g]			
*1|*1	78 (38.0%)		78 (18.7%)
*1|*28	91 (44.4%)		91 (21.8%)
*28|*28	17 (8.3%)		17 (4.1%)
Other	2 (1.0%)		2 (0.5%)
Missing/Not Done	17 (8.3%)		17 (4.1%)

[a] Not reported indicates local regulators did not allow collection of race or ethnicity information.
[b] BMI is calculated as BMI (kg/m^2) = (weight in kg) / (height in m)^2. [c] Based on Du Bois formula 0.007184 x weight(kg)^0.425 x height(cm)^0.725.
[d] Creatinine clearance is derived by using Cockcroft-Gault Equation, which may deviate from the value collected by the site at screening.
[e] Normal: Bilirubin (BILI) <= ULN and Aspartate transaminase (AST) <= ULN; Mild Hepatic Impairment (HI): 1) BILI <= ULN and AST > ULN or
2) ULN < BILI <= 1.5x ULN; Moderate HI: 1.5x ULN < BILI <= 3x ULN; Severe HI: BILI > 3x ULN.
[f] Collected only if required per local guidelines for participants receiving capecitabine.
[g] Baseline UGT1A1 includes 2 participants with samples after C1D1 (7 and 49 days after C1D1 respectively); Other includes *1|*36, *1|*37 and

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Table 15.1.4.2: Enrollment by Randomization Stratum and Treatment
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Prior Chemotherapy Regimens for Treatment of Metastatic Disease, n (%)[a]			
2 Lines	96 (46.8%)	102 (47.9%)	198 (47.4%)
3-4 Lines	109 (53.2%)	111 (52.1%)	220 (52.6%)
Visceral Metastasis, n (%)[a]			
Yes	196 (95.6%)	205 (96.2%)	401 (95.9%)
No	9 (4.4%)	8 (3.8%)	17 (4.1%)
Endocrine Therapy in the Metastatic Setting for at Least 6 Months, n (%)[a]			
Yes	183 (89.3%)	185 (86.9%)	368 (88.0%)
No	22 (10.7%)	28 (13.1%)	50 (12.0%)
Treatment of Physician Choice, n (%)[b]			
Eribulin		130 (61.0%)	130 (31.1%)
Capecitabine		22 (10.3%)	22 (5.3%)
Vinorelbine		61 (28.6%)	61 (14.6%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] The randomization strata data are based on IXRS.
[b] As specified by the incestigator prior to randomization

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Table 15.1.4.1: Baseline Disease Characteristics
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Screening ECOG Performance Status, n (%)			
0: Normal Activity	90 (43.9%)	99 (46.5%)	189 (45.2%)
1: Symptoms but Ambulatory	115 (56.1%)	114 (53.5%)	229 (54.8%)
Baseline Target/Non-Target Liver Lesion per RECIST1.1 per Local Investigator Review (LIR), n (%)			
Yes	181 (88.3%)	187 (87.8%)	368 (88.0%)
No	24 (11.7%)	26 (12.2%)	50 (12.0%)
Time from Metastatic Disease Diagnosis to Randomization (months) [a]			
N	205	213	418
Mean (SD)	53.7 (33.85)	52.3 (32.30)	53.0 (33.04)
Median	46.0	46.6	46.2
Minimum	6.7	3.0	3.0
Maximum	216.2	248.8	248.8

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Time from metastatic disease to randomization is defined as number of days divided by 30.4375 from date of confirmed metastatic disease to date of randomization.
For screening ECOG performance status, if screening ECOG was not available, C1D1 ECOG was used.

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Table 15.1.4.3: Breast Cancer History
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Breast Cancer Tumor Stage, n (%)			
TX	76 (37.1%)	71 (33.3%)	147 (35.2%)
T0	16 (7.8%)	10 (4.7%)	26 (6.2%)
T1	18 (8.8%)	33 (15.5%)	51 (12.2%)
T2	33 (16.1%)	44 (20.7%)	77 (18.4%)
T3	20 (9.8%)	14 (6.6%)	34 (8.1%)
T4	26 (12.7%)	20 (9.4%)	46 (11.0%)
Missing	16 (7.8%)	21 (9.9%)	37 (8.9%)
Breast Cancer Node Stage, n (%)			
NX	84 (41.0%)	76 (35.7%)	160 (38.3%)
N0	28 (13.7%)	38 (17.8%)	66 (15.8%)
N1	43 (21.0%)	39 (18.3%)	82 (19.6%)
N2	19 (9.3%)	23 (10.8%)	42 (10.0%)
N3	10 (4.9%)	15 (7.0%)	25 (6.0%)
Missing	21 (10.2%)	22 (10.3%)	43 (10.3%)
Breast Cancer Metastasis Stage, n (%)			
M0	0	1 (0.5%)	1 (0.2%)
M1	198 (96.6%)	208 (97.7%)	406 (97.1%)
Missing	7 (3.4%)	4 (1.9%)	11 (2.6%)
HER2 Status, n (%)			
Positive	0	2 (0.9%)	2 (0.5%)
Negative	205 (100.0%)	211 (99.1%)	416 (99.5%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Positive Estrogen Receptor or Progesterone Receptor are defined as >=1%.
[b] Positive denotes patient is either BRCA1 positive or BRCA2 positive. Negative denotes patient is both BRCA1 negative and BRCA2 negative.

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Table 15.1.4.3: Breast Cancer History
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Method of HER2 Status Diagnosis, n (%)			
IHC	149 (72.7%)	156 (73.2%)	305 (73.0%)
0	72 (35.1%)	85 (39.9%)	157 (37.6%)
1+	64 (31.2%)	53 (24.9%)	117 (28.0%)
2+	12 (5.9%)	17 (8.0%)	29 (6.9%)
Missing	1 (0.5%)	1 (0.5%)	2 (0.5%)
FISH	12 (5.9%)	15 (7.0%)	27 (6.5%)
Positive	0	1 (0.5%)	1 (0.2%)
Negative	12 (5.9%)	14 (6.6%)	26 (6.2%)
FISH and IHC	44 (21.5%)	40 (18.8%)	84 (20.1%)
Negative and 0	2 (1.0%)	8 (3.8%)	10 (2.4%)
Negative and 1+	5 (2.4%)	2 (0.9%)	7 (1.7%)
Negative and 2+	35 (17.1%)	29 (13.6%)	64 (15.3%)
Negative and 3+	2 (1.0%)	1 (0.5%)	3 (0.7%)
Missing Method	0	2 (0.9%)	2 (0.5%)
Estrogen Receptor Status, n (%)			
<1%	1 (0.5%)	4 (1.9%)	5 (1.2%)
Between 1-10%	8 (3.9%)	10 (4.7%)	18 (4.3%)
>10%	196 (95.6%)	195 (91.5%)	391 (93.5%)
Missing	0	4 (1.9%)	4 (1.0%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Positive Estrogen Receptor or Progesterone Receptor are defined as >=1%.
[b] Positive denotes patient is either BRCA1 positive or BRCA2 positive. Negative denotes patient is both BRCA1 negative and BRCA2 negative.

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Table 15.1.4.3: Breast Cancer History
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Progesterone Receptor Status, n (%)			
<1%	75 (36.6%)	81 (38.0%)	156 (37.3%)
Between 1-10%	37 (18.0%)	34 (16.0%)	71 (17.0%)
>10%	93 (45.4%)	93 (43.7%)	186 (44.5%)
Missing	0	5 (2.3%)	5 (1.2%)
Subjects with Either Estrogen Receptor or Progesterone Receptor Positive, n (%) [a]			
Yes	205 (100.0%)	209 (98.1%)	414 (99.0%)
No	0	0	0
Missing	0	4 (1.9%)	4 (1.0%)
Subjects with Both Estrogen Receptor and Progesterone Receptor Positive, n (%) [a]			
Yes	129 (62.9%)	123 (57.7%)	252 (60.3%)
No	76 (37.1%)	87 (40.8%)	163 (39.0%)
Missing	0	3 (1.4%)	3 (0.7%)
BRCA1 Mutation Status, n (%)			
Negative	91 (44.4%)	93 (43.7%)	184 (44.0%)
Positive	3 (1.5%)	3 (1.4%)	6 (1.4%)
Inconclusive	1 (0.5%)	1 (0.5%)	2 (0.5%)
Unknown	36 (17.6%)	37 (17.4%)	73 (17.5%)
Not Done	72 (35.1%)	76 (35.7%)	148 (35.4%)
Missing	2 (1.0%)	3 (1.4%)	5 (1.2%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Positive Estrogen Receptor or Progesterone Receptor are defined as >=1%.
[b] Positive denotes patient is either BRCA1 positive or BRCA2 positive. Negative denotes patient is both BRCA1 negative and BRCA2 negative.

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Table 15.1.4.3: Breast Cancer History
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Total (N = 418)
BRCA2 Mutation Status, n (%)			
Negative	84 (41.0%)	94 (44.1%)	178 (42.6%)
Positive	18 (8.8%)	3 (1.4%)	21 (5.0%)
Inconclusive	1 (0.5%)	1 (0.5%)	2 (0.5%)
Unknown	29 (14.1%)	35 (16.4%)	64 (15.3%)
Not Done	71 (34.6%)	77 (36.2%)	148 (35.4%)
Missing	2 (1.0%)	3 (1.4%)	5 (1.2%)
BRCA1 / BRCA2 Mutation Status, n (%) [b]			
Negative	83 (40.5%)	90 (42.3%)	173 (41.4%)
Positive	19 (9.3%)	6 (2.8%)	25 (6.0%)
Missing	103 (50.2%)	117 (54.9%)	220 (52.6%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Positive Estrogen Receptor or Progesterone Receptor are defined as >=1%.
[b] Positive denotes patient is either BRCA1 positive or BRCA2 positive. Negative denotes patient is both BRCA1 negative and BRCA2 negative.

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Table 15.1.5.1: Prior Systemic Anticancer Therapy
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Number of Prior Systemic Anti-cancer Regimens			
N	205	213	418
Mean (SD)	7.0 (2.28)	7.0 (2.16)	7.0 (2.22)
Median	7.0	7.0	7.0
Min, Max	3, 15	3, 16	3, 16
Number of Prior Systemic Anti-cancer Regimens by Category, n(%)			
3	4 (2.0%)	2 (0.9%)	6 (1.4%)
4	19 (9.3%)	18 (8.5%)	37 (8.9%)
>4	182 (88.8%)	193 (90.6%)	375 (89.7%)
Number of Prior Systemic Chemotherapy Regimen			
N	205	213	418
Mean (SD)	3.5 (1.10)	3.6 (1.07)	3.6 (1.08)
Median	3.0	4.0	3.0
Min, Max	1, 7	2, 7	1, 7
Number of Prior Systemic Chemotherapy Regimen by Category, n(%)			
1	1 (0.5%)	0	1 (0.2%)
2	35 (17.1%)	34 (16.0%)	69 (16.5%)
3	71 (34.6%)	72 (33.8%)	143 (34.2%)
4	60 (29.3%)	69 (32.4%)	129 (30.9%)
>4	38 (18.5%)	38 (17.8%)	76 (18.2%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Number of prior lines of chemotherapy for treatment of metastatic disease is counted as the number of chemotherapy regimens in the metastatic setting. It is based on the collected data from prior anti-cancer therapy eCRF and not from site reported prior number of chemotherapy regimens for treatment of metastatic disease in IXRS, which may include the additional line from neo/adjuvant chemotherapy if participant early relapsed.
[b] Early relapse is defined as relapse to metastatic disease within 1 year of the end of neo/adjuvant chemotherapy. participants without chemotherapy in

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Table 15.1.5.1: Prior Systemic Anticancer Therapy
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Number of Prior Lines of Chemotherapy in Metastatic Setting, n(%) [a]			
1	6 (2.9%)	2 (0.9%)	8 (1.9%)
>1	199 (97.1%)	211 (99.1%)	410 (98.1%)
Number of Prior Lines of Chemotherapy in Metastatic Setting, n(%) [a]			
<=2	96 (46.8%)	112 (52.6%)	208 (49.8%)
>=3	109 (53.2%)	101 (47.4%)	210 (50.2%)
Number of Prior Lines of Chemotherapy in Metastatic Setting, n(%) [a]			
1	6 (2.9%)	2 (0.9%)	8 (1.9%)
2	90 (43.9%)	110 (51.6%)	200 (47.8%)
3	71 (34.6%)	63 (29.6%)	134 (32.1%)
4	34 (16.6%)	38 (17.8%)	72 (17.2%)
5	3 (1.5%)	0	3 (0.7%)
6	1 (0.5%)	0	1 (0.2%)
Number of Prior Lines of Chemotherapy in Metastatic Setting [a]			
N	205	213	418
Mean (SD)	3 (0.9)	3 (0.8)	3 (0.8)
Median	3	2	3
Min, Max	1, 6	1, 4	1, 6

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Number of prior lines of chemotherapy for treatment of metastatic disease is counted as the number of chemotherapy regimens in the metastatic setting. It is based on the collected data from prior anti-cancer therapy eCRF and not from site reported prior number of chemotherapy regimens for treatment of metastatic disease in IXRS, which may include the additional line from neo/adjuvant chemotherapy if participant early relapsed.
[b] Early relapse is defined as relapse to metastatic disease within 1 year of the end of neo/adjuvant chemotherapy. participants without chemotherapy in

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Table 15.1.5.1: Prior Systemic Anticancer Therapy
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Early Relapse, n(%) [b]			
Yes	13 (6.3%)	17 (8.0%)	30 (7.2%)
No	185 (90.2%)	192 (90.1%)	377 (90.2%)
Unknown	7 (3.4%)	4 (1.9%)	11 (2.6%)
Prior CDK 4/6 use, n(%)			
Yes	205 (100.0%)	213 (100.0%)	418 (100.0%)
Prior CDK 4/6 use, n(%) [c]			
<=12 months	118 (57.6%)	128 (60.1%)	246 (58.9%)
>12 months	82 (40.0%)	82 (38.5%)	164 (39.2%)
Missing	5 (2.4%)	3 (1.4%)	8 (1.9%)
Chemotherapy in neo/adjuvant setting, n(%)			
Yes	125 (61.0%)	145 (68.1%)	270 (64.6%)
No	80 (39.0%)	68 (31.9%)	148 (35.4%)
Reason for Administration of Anti-cancer Treatment, n(%)			
Neoadjuvant	45 (22.0%)	53 (24.9%)	98 (23.4%)
Adjuvant	136 (66.3%)	160 (75.1%)	296 (70.8%)
Advanced/Metastatic	205 (100.0%)	213 (100.0%)	418 (100.0%)
Other	6 (2.9%)	6 (2.8%)	12 (2.9%)
Unknown	2 (1.0%)	1 (0.5%)	3 (0.7%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Number of prior lines of chemotherapy for treatment of metastatic disease is counted as the number of chemotherapy regimens in the metastatic setting. It is based on the collected data from prior anti-cancer therapy eCRF and not from site reported prior number of chemotherapy regimens for treatment of metastatic disease in IXRS, which may include the additional line from neo/adjuvant chemotherapy if participant early relapsed.
[b] Early relapse is defined as relapse to metastatic disease within 1 year of the end of neo/adjuvant chemotherapy. participants without chemotherapy in

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Table 15.1.5.1: Prior Systemic Anticancer Therapy
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Total (N=418)
Best Response for the Last Therapy Before Entering Study, n(%)			
CR	0	1 (0.5%)	1 (0.2%)
PR	24 (11.7%)	18 (8.5%)	42 (10.0%)
SD	47 (22.9%)	38 (17.8%)	85 (20.3%)
PD	87 (42.4%)	101 (47.4%)	188 (45.0%)
Not Reported/Not Available	38 (18.5%)	49 (23.0%)	87 (20.8%)
Not Applicable	7 (3.4%)	4 (1.9%)	11 (2.6%)
Missing	2 (1.0%)	2 (0.9%)	4 (1.0%)
Time from Last Disease Progression to Randomization (months)			
N	205	212	417
Mean (SD)	1.1 (0.97)	1.2 (1.19)	1.1 (1.09)
Median	0.9	0.9	0.9
Min, Max	0.2, 11.3	0.1, 11.7	0.1, 11.7

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
[a] Number of prior lines of chemotherapy for treatment of metastatic disease is counted as the number of chemotherapy regimens in the metastatic setting. It is based on the collected data from prior anti-cancer therapy eCRF and not from site reported prior number of chemotherapy regimens for treatment of metastatic disease in IXRS, which may include the additional line from neo/adjuvant chemotherapy if participant early relapsed.
[b] Early relapse is defined as relapse to metastatic disease within 1 year of the end of neo/adjuvant chemotherapy. participants without chemotherapy in

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Table 15.1.5.2: Prior Systemic Anticancer Therapy by Preferred Drug name
ITT Population
Excluding Participants Pre-selected to Gemcitabine

Preferred Drug Name	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Subjects with Any Prior Anti-cancer Therapy, n (%)	205 (100.0%)	213 (100.0%)	418 (100.0%)
Palbociclib	176 (85.9%)	175 (82.2%)	351 (84.0%)
Fulvestrant	175 (85.4%)	174 (81.7%)	349 (83.5%)
Capecitabine	164 (80.0%)	179 (84.0%)	343 (82.1%)
Paclitaxel	167 (81.5%)	166 (77.9%)	333 (79.7%)
Letrozole	144 (70.2%)	168 (78.9%)	312 (74.6%)
Cyclophosphamide	151 (73.7%)	160 (75.1%)	311 (74.4%)
Tamoxifen	120 (58.5%)	129 (60.6%)	249 (59.6%)
Exemestane	109 (53.2%)	98 (46.0%)	207 (49.5%)
Docetaxel	79 (38.5%)	95 (44.6%)	174 (41.6%)
Everolimus	88 (42.9%)	85 (39.9%)	173 (41.4%)
Doxorubicin	89 (43.4%)	79 (37.1%)	168 (40.2%)
Epirubicin	57 (27.8%)	76 (35.7%)	133 (31.8%)
Anastrozole	61 (29.8%)	49 (23.0%)	110 (26.3%)
Fluorouracil	47 (22.9%)	59 (27.7%)	106 (25.4%)
Eribulin	53 (25.9%)	49 (23.0%)	102 (24.4%)
Bevacizumab	40 (19.5%)	33 (15.5%)	73 (17.5%)
Gemcitabine	30 (14.6%)	34 (16.0%)	64 (15.3%)
Carboplatin	27 (13.2%)	33 (15.5%)	60 (14.4%)
Abemaciclib	22 (10.7%)	34 (16.0%)	56 (13.4%)
Ribociclib	19 (9.3%)	21 (9.9%)	40 (9.6%)
Alpelisib	16 (7.8%)	20 (9.4%)	36 (8.6%)
Denosumab	18 (8.8%)	15 (7.0%)	33 (7.9%)
Vinorelbine	17 (8.3%)	15 (7.0%)	32 (7.7%)
Paclitaxel Nanoparticle Albumin-Bound	12 (5.9%)	19 (8.9%)	31 (7.4%)
Goserelin Acetate	16 (7.8%)	12 (5.6%)	28 (6.7%)
Goserelin	14 (6.8%)	12 (5.6%)	26 (6.2%)
Pegylated Liposomal Doxorubicin Hydrochloride	15 (7.3%)	11 (5.2%)	26 (6.2%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
Subjects were counted only once for each preferred drug name.
WHO Drug Dictionary (Version BMAR22) was used for coding.

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Table 15.1.5.2: Prior Systemic Anticancer Therapy by Preferred Drug name
ITT Population
Excluding Participants Pre-selected to Gemcitabine

Preferred Drug Name	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Trastuzumab	15 (7.3%)	8 (3.8%)	23 (5.5%)
Vinorelbine Tartrate	13 (6.3%)	10 (4.7%)	23 (5.5%)
Methotrexate	16 (7.8%)	6 (2.8%)	22 (5.3%)
Investigational Drug	7 (3.4%)	13 (6.1%)	20 (4.8%)
Leuprorelin Acetate	8 (3.9%)	9 (4.2%)	17 (4.1%)
Gemcitabine Hydrochloride	7 (3.4%)	9 (4.2%)	16 (3.8%)
Olaparib	6 (2.9%)	10 (4.7%)	16 (3.8%)
Zoledronic Acid	9 (4.4%)	7 (3.3%)	16 (3.8%)
Liposomal Doxorubicin	8 (3.9%)	5 (2.3%)	13 (3.1%)
Pembrolizumab	8 (3.9%)	4 (1.9%)	12 (2.9%)
Pertuzumab	7 (3.4%)	4 (1.9%)	11 (2.6%)
Leuprorelin	5 (2.4%)	5 (2.3%)	10 (2.4%)
Cisplatin	4 (2.0%)	5 (2.3%)	9 (2.2%)
Talazoparib	8 (3.9%)	1 (0.5%)	9 (2.2%)
Epirubicin Hydrochloride	2 (1.0%)	6 (2.8%)	8 (1.9%)
Gonadorelin Diacetate Tetrahydrate	3 (1.5%)	5 (2.3%)	8 (1.9%)
Liposomal Doxorubicin Hydrochloride	2 (1.0%)	5 (2.3%)	7 (1.7%)
Triptorelin	2 (1.0%)	5 (2.3%)	7 (1.7%)
Atezolizumab	3 (1.5%)	3 (1.4%)	6 (1.4%)
Doxorubicin Hydrochloride	1 (0.5%)	4 (1.9%)	5 (1.2%)
Etoposide	1 (0.5%)	4 (1.9%)	5 (1.2%)
Inavolisib	3 (1.5%)	2 (0.9%)	5 (1.2%)
Megestrol Acetate	3 (1.5%)	2 (0.9%)	5 (1.2%)
Neratinib	2 (1.0%)	3 (1.4%)	5 (1.2%)
Tamoxifen Citrate	2 (1.0%)	3 (1.4%)	5 (1.2%)
Tesetaxel	2 (1.0%)	3 (1.4%)	5 (1.2%)
Balixafortide	3 (1.5%)	1 (0.5%)	4 (1.0%)
Eribulin Mesilate	1 (0.5%)	3 (1.4%)	4 (1.0%)
Ixabepilone	2 (1.0%)	2 (0.9%)	4 (1.0%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
Subjects were counted only once for each preferred drug name.
WHO Drug Dictionary (Version BMAR22) was used for coding.

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Table 15.1.5.2: Prior Systemic Anticancer Therapy by Preferred Drug name
ITT Population
Excluding Participants Pre-selected to Gemcitabine

Preferred Drug Name	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Selective Estrogen Receptor Modulators	2 (1.0%)	2 (0.9%)	4 (1.0%)
Taselisib	1 (0.5%)	3 (1.4%)	4 (1.0%)
Trastuzumab Emtansine	3 (1.5%)	1 (0.5%)	4 (1.0%)
Alisertib	0	3 (1.4%)	3 (0.7%)
Avelumab	2 (1.0%)	1 (0.5%)	3 (0.7%)
Durvalumab	1 (0.5%)	2 (0.9%)	3 (0.7%)
Enzalutamide	1 (0.5%)	2 (0.9%)	3 (0.7%)
Gedatolisib	1 (0.5%)	2 (0.9%)	3 (0.7%)
Gonadotropin Releasing Hormone Analogues	1 (0.5%)	2 (0.9%)	3 (0.7%)
Ipatasertib	1 (0.5%)	2 (0.9%)	3 (0.7%)
Ipilimumab	3 (1.5%)	0	3 (0.7%)
Lenvatinib	3 (1.5%)	0	3 (0.7%)
Mitomycin	0	3 (1.4%)	3 (0.7%)
Nivolumab	3 (1.5%)	0	3 (0.7%)
Other Antineoplastic Agents	2 (1.0%)	1 (0.5%)	3 (0.7%)
Pegylated Liposomal Doxorubicin	1 (0.5%)	2 (0.9%)	3 (0.7%)
Sapanisertib	2 (1.0%)	1 (0.5%)	3 (0.7%)
Xentuzumab	1 (0.5%)	2 (0.9%)	3 (0.7%)
Zenocutuzumab	2 (1.0%)	1 (0.5%)	3 (0.7%)
Aromatase Inhibitors	1 (0.5%)	1 (0.5%)	2 (0.5%)
Azacitidine	2 (1.0%)	0	2 (0.5%)
Cirmtuzumab	1 (0.5%)	1 (0.5%)	2 (0.5%)
Elacestrant	1 (0.5%)	1 (0.5%)	2 (0.5%)
Enobosarm	0	2 (0.9%)	2 (0.5%)
Entinostat	0	2 (0.9%)	2 (0.5%)
Placebo	2 (1.0%)	0	2 (0.5%)
Rintodestrant	0	2 (0.9%)	2 (0.5%)
Sgn Liv1a	0	2 (0.9%)	2 (0.5%)
Trastuzumab Deruxtecan	1 (0.5%)	1 (0.5%)	2 (0.5%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
Subjects were counted only once for each preferred drug name.
WHO Drug Dictionary (Version BMAR22) was used for coding.

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Table 15.1.5.2: Prior Systemic Anticancer Therapy by Preferred Drug name
ITT Population
Excluding Participants Pre-selected to Gemcitabine

Preferred Drug Name	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Vincristine	1 (0.5%)	1 (0.5%)	2 (0.5%)
Amcenestrant	0	1 (0.5%)	1 (0.2%)
Amilomer	0	1 (0.5%)	1 (0.2%)
Anti-Estrogens	0	1 (0.5%)	1 (0.2%)
Azd 9496	1 (0.5%)	0	1 (0.2%)
Bay 1125976	1 (0.5%)	0	1 (0.2%)
Bazedoxifene	0	1 (0.5%)	1 (0.2%)
Bevacizumab Awwb	0	1 (0.5%)	1 (0.2%)
Bicalutamide	1 (0.5%)	0	1 (0.2%)
Bisphosphonates	0	1 (0.5%)	1 (0.2%)
Bleomycin	1 (0.5%)	0	1 (0.2%)
Brilanestrant	0	1 (0.5%)	1 (0.2%)
Buparlisib	0	1 (0.5%)	1 (0.2%)
Calcium	0	1 (0.5%)	1 (0.2%)
Calcium Folinate	0	1 (0.5%)	1 (0.2%)
Capivasertib	1 (0.5%)	0	1 (0.2%)
Dasatinib	1 (0.5%)	0	1 (0.2%)
Derazantinib	1 (0.5%)	0	1 (0.2%)
Elimusertib	0	1 (0.5%)	1 (0.2%)
Estradiol	0	1 (0.5%)	1 (0.2%)
Ethiodized Oil	0	1 (0.5%)	1 (0.2%)
Ezabenlimab	1 (0.5%)	0	1 (0.2%)
Folinic Acid	0	1 (0.5%)	1 (0.2%)
Gene Therapy	0	1 (0.5%)	1 (0.2%)
Gonadotropin-Releasing Hormones	1 (0.5%)	0	1 (0.2%)
Ibandronic Acid	1 (0.5%)	0	1 (0.2%)
Lucitanib	1 (0.5%)	0	1 (0.2%)
Lurbinectedin	1 (0.5%)	0	1 (0.2%)
Medroxyprogesterone	1 (0.5%)	0	1 (0.2%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
Subjects were counted only once for each preferred drug name.
WHO Drug Dictionary (Version BMAR22) was used for coding.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.1.5.2: Prior Systemic Anticancer Therapy by Preferred Drug name
ITT Population
Excluding Participants Pre-selected to Gemcitabine

Preferred Drug Name	SG (N = 205)	TPC (N = 213)	Total (N = 418)
Megestrol	0	1 (0.5%)	1 (0.2%)
Methotrexate Sodium	1 (0.5%)	0	1 (0.2%)
Mitoxantrone	1 (0.5%)	0	1 (0.2%)
Mitoxantrone Hydrochloride	1 (0.5%)	0	1 (0.2%)
Molibresib	1 (0.5%)	0	1 (0.2%)
Nintedanib	1 (0.5%)	0	1 (0.2%)
Octreotide Acetate	0	1 (0.5%)	1 (0.2%)
Other Vaccines	1 (0.5%)	0	1 (0.2%)
Pamidronate Disodium	1 (0.5%)	0	1 (0.2%)
Pm14	1 (0.5%)	0	1 (0.2%)
Ribociclib Succinate	0	1 (0.5%)	1 (0.2%)
Rucaparib	1 (0.5%)	0	1 (0.2%)
Stn-Klh Vaccine	0	1 (0.5%)	1 (0.2%)
Talazoparib Tosylate	0	1 (0.5%)	1 (0.2%)
Talimogene Laherparepvec	0	1 (0.5%)	1 (0.2%)
Temozolomide	0	1 (0.5%)	1 (0.2%)
Toremifene	1 (0.5%)	0	1 (0.2%)
Trametinib	1 (0.5%)	0	1 (0.2%)
Vincristine Sulfate	1 (0.5%)	0	1 (0.2%)

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
Subjects were counted only once for each preferred drug name.
WHO Drug Dictionary (Version BMAR22) was used for coding.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Anhang 4-G 2: Behandlungs- und Beobachtungsdauern

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Table 15.3.1.1: Summary of Treatment Exposure
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N = 201)	Eribulin (N = 120)	Capecitabine (N = 22)	Vinorelbine (N = 52)	TPC (N = 194)
Treatment Duration (months) [a]					
N	201	120	22	52	194
Mean	5.61	4.34	4.80	1.94	3.75
SD	5.554	4.005	4.101	1.808	3.717
Median	3.98	3.37	4.53	1.18	2.56
Minimum	0.03	0.03	0.23	0.03	0.03
Maximum	30.36	22.18	12.91	8.05	22.18
>= 3 months, n (%)	120 (59.7%)	66 (55.0%)	13 (59.1%)	12 (23.1%)	91 (46.9%)
>= 6 months, n (%)	70 (34.8%)	33 (27.5%)	5 (22.7%)	3 (5.8%)	41 (21.1%)
>= 12 months, n (%)	26 (12.9%)	5 (4.2%)	2 (9.1%)	0	7 (3.6%)
>= 24 months, n (%)	3 (1.5%)	0	0	0	0
Number of Cycles Received					
N	201	120	22	52	194
Mean	8.31	6.70	7.09	3.12	5.78
SD	7.700	5.509	5.690	2.120	5.105
Median	6.00	5.50	6.50	2.00	4.00
Minimum	1.00	1.00	1.00	1.00	1.00
Maximum	43.00	33.00	19.00	10.00	33.00

[a] Treatment duration (in months) is (date of the last treatment administration - date of the first treatment administration +1)/30.4375.
[b] The dose unit for sacituzumab govitecan is mg/kg. The dose unit for all Treatment of Physician's Choice therapies is mg/m^2.
[c] The number of durations of infusion interruptions, and duration of each infusion interruption is summarized.
[d] Relative dose intensity (in %) is calculated as cumulative dosage received (mg/kg or mg/m^2) / total assigned dosage (mg/kg or mg/m^2) x 100.
Total assigned dosage is calculated based on target dosage and number of doses subjects planned while on treatment.
No dose delay information is collected for the group of Capecitabine.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.3.1.1: Summary of Treatment Exposure
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N = 201)	Eribulin (N = 120)	Capecitabine (N = 22)	Vinorelbine (N = 52)	TPC (N = 194)
Cumulative Dosage (unit)[b]					
N	199	117	22	51	
Mean	144.65	15.43	193673.35	172.91	
SD	130.773	12.758	163033.753	128.078	
Median	110.11	12.27	184336.41	118.87	
Minimum	9.88	1.22	12828.38	14.70	
Maximum	620.14	67.47	548503.56	524.89	
Duration of Infusion Interruptions (hours)[c]					
N	2	0		0	
Mean	0.85				
SD	0.141				
Median	0.85				
Minimum	0.75				
Maximum	0.95				
Number of Subjects with Dose Reductions, n (%)					
Any	70 (34.8%)	49 (40.8%)	6 (27.3%)	20 (38.5%)	75 (38.7%)
1	52 (25.9%)	40 (33.3%)	4 (18.2%)	16 (30.8%)	60 (30.9%)
2	17 (8.5%)	7 (5.8%)	2 (9.1%)	3 (5.8%)	12 (6.2%)
3	0	0	0	1 (1.9%)	1 (0.5%)
>3	1 (0.5%)	2 (1.7%)	0	0	2 (1.0%)

[a] Treatment duration (in months) is (date of the last treatment administration - date of the first treatment administration +1)/30.4375.
[b] The dose unit for sacituzumab govitecan is mg/kg. The dose unit for all Treatment of Physician's Choice therapies is mg/m^2.
[c] The number of durations of infusion interruptions, and duration of each infusion interruption is summarized.
[d] Relative dose intensity (in %) is calculated as cumulative dosage received (mg/kg or mg/m^2) / total assigned dosage (mg/kg or mg/m^2) x 100.
Total assigned dosage is calculated based on target dosage and number of doses subjects planned while on treatment.
No dose delay information is collected for the group of Capecitabine.

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Table 15.3.1.1: Summary of Treatment Exposure
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N = 201)	Eribulin (N = 120)	Capecitabine (N = 22)	Vinorelbine (N = 52)	TPC (N = 194)
Time to First Dose Reduction (months)					
N	70	49	6	20	75
Mean	2.40	2.30	1.61	0.78	1.84
SD	2.269	2.441	1.393	0.508	2.124
Median	1.51	1.15	1.18	0.71	0.95
Minimum	0.23	0.03	0.03	0.03	0.03
Maximum	11.60	8.54	3.75	2.37	8.54
Relative Dose Intensity (%) [d]					
N	199	117	22	51	
Mean	91.75	89.82	85.86	89.99	
SD	12.235	15.736	28.386	14.014	
Median	99.29	96.42	90.79	98.00	
Minimum	50.00	14.26	31.39	56.24	
Maximum	106.06	121.55	145.81	105.07	
Relative Dose Intensity, n (%)					
<70%	15 (7.5%)	14 (11.7%)	4 (18.2%)	10 (19.2%)	
70% to <90%	50 (24.9%)	27 (22.5%)	7 (31.8%)	7 (13.5%)	
90% to <110%	134 (66.7%)	75 (62.5%)	9 (40.9%)	34 (65.4%)	
>=110%	0	1 (0.8%)	2 (9.1%)	0	

[a] Treatment duration (in months) is (date of the last treatment administration - date of the first treatment administration +1)/30.4375.
[b] The dose unit for sacituzumab govitecan is mg/kg. The dose unit for all Treatment of Physician's Choice therapies is mg/m^2.
[c] The number of durations of infusion interruptions, and duration of each infusion interruption is summarized.
[d] Relative dose intensity (in %) is calculated as cumulative dosage received (mg/kg or mg/m^2) / total assigned dosage (mg/kg or mg/m^2) x 100.
Total assigned dosage is calculated based on target dosage and number of doses subjects planned while on treatment.
No dose delay information is collected for the group of Capecitabine.

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Table 15.2.2.8: Follow-up Duration of Overall Survival (OS) at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)
Number of Deaths [n (%)]	165 (80.5%)	176 (82.6%)
Number of Subjects Alive [n (%)]	40 (19.5%)	37 (17.4%)
Follow-up Duration of OS (months)		
N	205	213
Mean (SD)	15.17 (8.837)	13.41 (9.048)
Median	13.93	10.78
Q1, Q3	8.90, 20.93	5.68, 20.67
Min, Max	0.03, 36.47	0.03, 38.05

The denominator is the number of patients in the ITT Population excluding those assigned to Gemcitabine before randomized for each treatment group.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
For patients who are still alive, the last known alive date were used in the descriptive summary statistics.
For min and max, + indicated participants are censored at last known alive date.
Final OS data cut is at 01Dec2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
Source: .../germandossier/jan2023/prog/t-os-fud-fos-exg.sas v9.4 Output file: t-os-fud-fos-exg.pdf 12MAY2023:11:14 Page 1 of 1

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Table 15.2.2.9: Follow-up Duration of Overall Survival (OS) at Final OS Data
ITT Population
Only including participants never dosed, excluding participants pre-selected to Gemcitabine

	SG (N=4)	TPC (N=19)
Number of Deaths [n (%)]	3 (75.0%)	17 (89.5%)
Number of Subjects Alive [n (%)]	1 (25.0%)	2 (10.5%)
Follow-up Duration of OS (months)		
N	4	19
Mean (SD)	5.92 (6.593)	7.90 (7.469)
Median	5.27	6.37
Q1, Q3	0.33, 11.52	1.45, 10.35
Min, Max	0.03, 13.11	0.03, 28.52

The denominator is the number of patients in the ITT Population but never dosed excluding participants assigned to Gemcitabine before randomized for each treatment group.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
For patients who are still alive, the last known alive date were used in the descriptive summary statistics.
For min and max, + indicated participants are censored at last known alive date.
Final OS data cut is at 01Dec2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
Source: .../germandossier/jan2023/prog/t-os-fud2-fos-exg.sas v9.4 Output file: t-os-fud2-fos-exg.pdf 12MAY2023:11:14 Page 1 of 1

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Table 15.2.1.5: Follow-up Duration of Progression Free Survival (PFS) per BICR for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)
Number of Subjects with Disease Progression or Death [n (%)]	135 (65.9%)	142 (66.7%)
Number of Subjects Censored [n (%)]	70 (34.1%)	71 (33.3%)
Follow-up Duration of PFS (months)		
N	205	213
Mean (SD)	5.02 (4.875)	3.44 (3.230)
Median	3.71	2.60
Q1, Q3	1.48, 7.00	1.28, 5.36
Min, Max	0.03, 29.08	0.03, 16.59

PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
Participants who are still alive by the data cut date without documented disease progression will be censored at their last evaluable tumor assessment
Follow-up duration of PFS is the number of months from randomization date to the death date or disease progression date, which comes first, or date of being censored, if no PFS event.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
Source: .../germandossier/jan2023/prog/t-pfs-bicr-fud-ia2-exg.sas v9.4 Output file: t-pfs-bicr-fud-ia2-exg.pdf 28FEB2023:11:13 Page 1 of 1

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Table 15.2.5.1: Follow-up Duration for Tumor Assessments
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)
Follow-up Duration of Tumor Assessments (months)		
Total Patients	194	175
Mean (SD)	6.06 (5.387)	4.41 (3.706)
Median	4.40	3.32
Q1, Q3	1.61, 8.25	1.45, 5.78
Min, Max	0.33, 29.08	0.26, 22.70

Follow up duration starts from the randomization date to the last available assessment date on or before the data cut off
This table includes those participants who have at least one image assessment per BICR on or after randomziation date
Follow-up Duration of Tumor Assessment is the number of months from randomziation date to the last available image assessment per BICR before the new anti-cancer therapy.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.15.1.1.2
Summary of Follow-up Duration for EORTC QLQ-C30
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Statistic	SG (N=174)	TPC (N=165)	Overall (N=339)
N	174	165	339
Mean (SD)	6.8 (5.65)	4.7 (3.81)	5.8 (4.94)
95% CI	5.9, 7.6	4.1, 5.3	5.3, 6.3
Median	5.4	3.7	4.3
Q1, Q3	2.6, 8.3	1.8, 6.5	2.1, 7.6
Min, Max	0.0, 30.4	0.3, 22.9	0.0, 30.4

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Follow-up duration is defined as time from start of treatment until final study visit (or date of last questionnaire completion if occurred earlier) in months (days/30.4375). CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.1.2.2
Summary of Follow-up Duration for EQ-5D VAS
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Statistic	SG (N=175)	TPC (N=164)	Overall (N=339)
N	175	163	338
Mean (SD)	6.6 (5.63)	4.8 (3.82)	5.7 (4.93)
95% CI	5.8, 7.5	4.2, 5.4	5.2, 6.3
Median	5.0	3.9	4.3
Q1, Q3	2.6, 8.2	1.8, 6.7	2.1, 7.6
Min, Max	0.0, 30.4	-0.1, 22.9	-0.1, 30.4

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. Follow-up duration is defined as time from start of treatment until final study visit (or date of last questionnaire completion if occurred earlier) in months (days/30.4375). CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SD = Standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale

Table 15.15.1.3.2
Summary of Follow-up Duration for PRO-CTCAE
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Statistic	SG (N=201)	TPC (N=194)	Overall (N=395)
N	197	191	388
Mean (SD)	6.4 (5.58)	4.2 (3.84)	5.3 (4.92)
95% CI	5.6, 7.2	3.7, 4.8	4.8, 5.8
Median	5.0	3.1	4.2
Q1, Q3	2.1, 8.1	1.4, 5.9	1.6, 7.3
Min, Max	-0.8, 30.4	-0.2, 22.9	-0.8, 30.4

Note:"Safety population" is defined as all ITT subjects who have received at least one dose of study drug. Follow-up duration is defined as time from start of treatment until final study visit (or date of last questionnaire completion if occurred earlier) in months (days/30.4375). CI = Confidence Interval; SD = standard deviation; SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.

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Table 15.3.1.2: Follow-up Duration for Safety
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)
Follow-up Duration for Safety (months)		
N	201	194
Mean (SD)	6.49 (5.509)	4.62 (3.748)
Median	4.96	3.53
Q1, Q3	2.17, 8.18	1.94, 6.24
Min, Max	0.20, 30.36	0.26, 23.16

Follow-up duration is time (months) from first dose date to 30 days after treatment and shortened to death date or last contact if occurred earlier.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Anhang 4-G 3: Gesamtüberleben

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Table 15.2.2.2: Overall Survival (OS) for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Subjects with Events [n (%)]	145 (70.7%)	153 (71.8%)	
Subjects without Events (Censored) [n (%)]	60 (29.3%)	60 (28.2%)	
Median OS (95% CI) [a]	14.1 (12.8, 15.5)	11.3 (10.1, 12.9)	
Log-rank P-value (Stratified) [b]			0.2060
Stratified Cox Regression Analysis [b]			
Hazard Ratio (Relative to TPC)			0.862
95% CI for Hazard Ratio			(0.686, 1.085)
Kaplan-Meier Estimate of OS Rate (%) (95% CI) [c]			
At 6 Months	83.1 (77.2, 87.6)	76.1 (69.7, 81.4)	
At 9 Months	75.1 (68.5, 80.5)	64.8 (57.8, 70.9)	
At 12 Months	60.4 (53.2, 66.8)	47.5 (40.5, 54.2)	

OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[b] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).
[c] OS rate is the proportion of participants alive.

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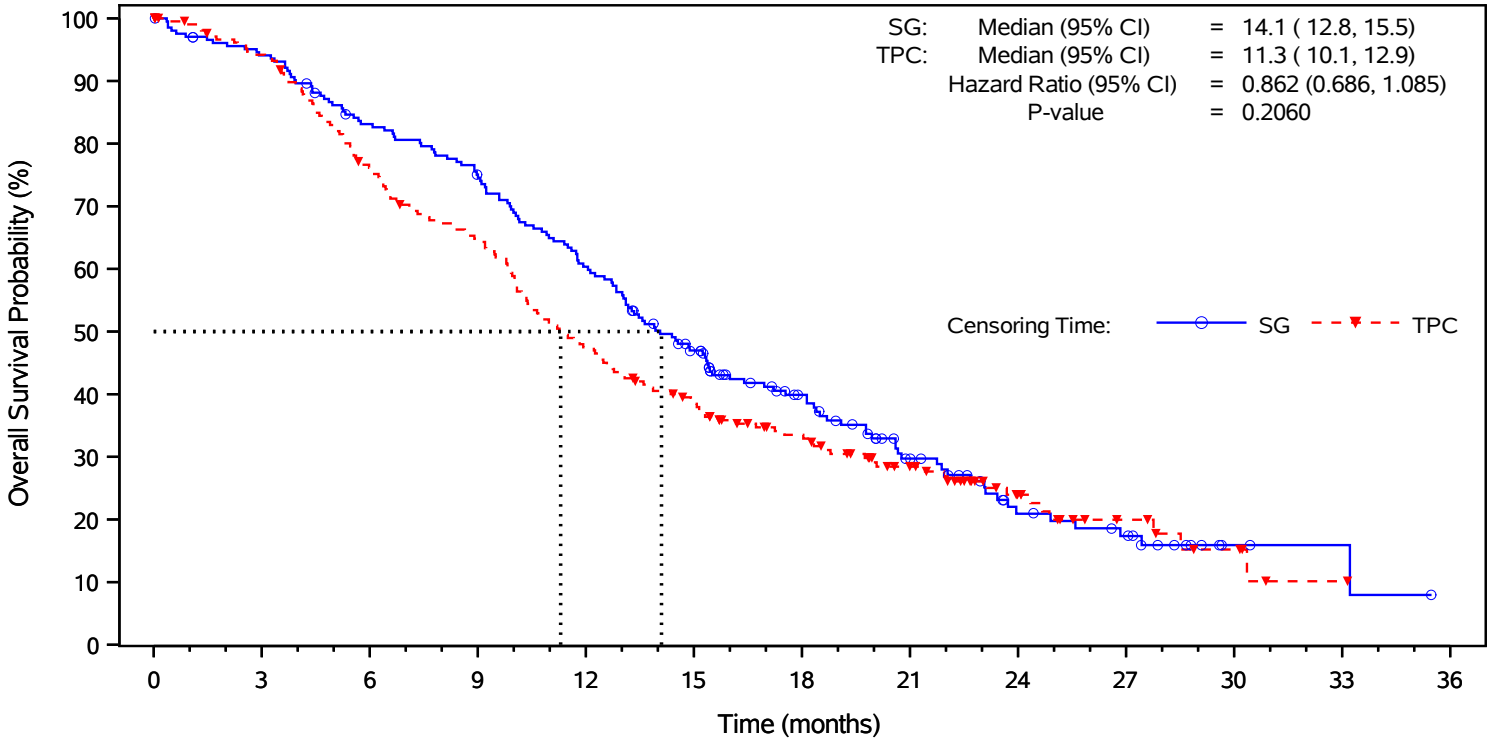
Study IMMU-132-09

Figure 15.2.2.2: Kaplan-Meier Estimates of Overall Survival (OS) for Interim Analysis 2 Data
ITT Population
Excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	205 (0)	190 (12)	165 (34)	148 (50)	119 (79)	87 (105)	59 (117)	35 (131)	19 (140)	14 (143)	3 (144)	2 (144)	0 (145)
TPC	213 (0)	194 (12)	155 (49)	131 (72)	96 (107)	74 (125)	56 (134)	38 (142)	20 (147)	10 (150)	5 (152)	1 (153)	0 (153)

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Table 15.2.2.7: Overall Survival (OS) at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Subjects with Events [n (%)]	165 (80.5%)	176 (82.6%)	
Subjects without Events (Censored) [n (%)]	40 (19.5%)	37 (17.4%)	
Median OS (95% CI) [a]	14.4 (12.8, 16.0)	11.2 (10.1, 12.8)	
Log-rank P-value (Stratified) [b]			0.1363
Stratified Cox Regression Analysis [b]			
Hazard Ratio (Relative to TPC)			0.850
95% CI for Hazard Ratio			(0.686, 1.053)
Kaplan-Meier Estimate of OS Rate (%) (95% CI) [c]			
At 6 Months	82.8 (76.8, 87.3)	75.6 (69.2, 80.9)	
At 9 Months	74.8 (68.3, 80.3)	64.5 (57.6, 70.6)	
At 12 Months	60.5 (53.4, 66.8)	47.1 (40.1, 53.7)	

The denominator is the number of patients in the ITT Population excluding those assigned to Gemcitabine before randomized for each treatment group.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
[a] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[b] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).
[c] OS rate is the proportion of participants alive.
Final OS data cut is at 12/1/2022.

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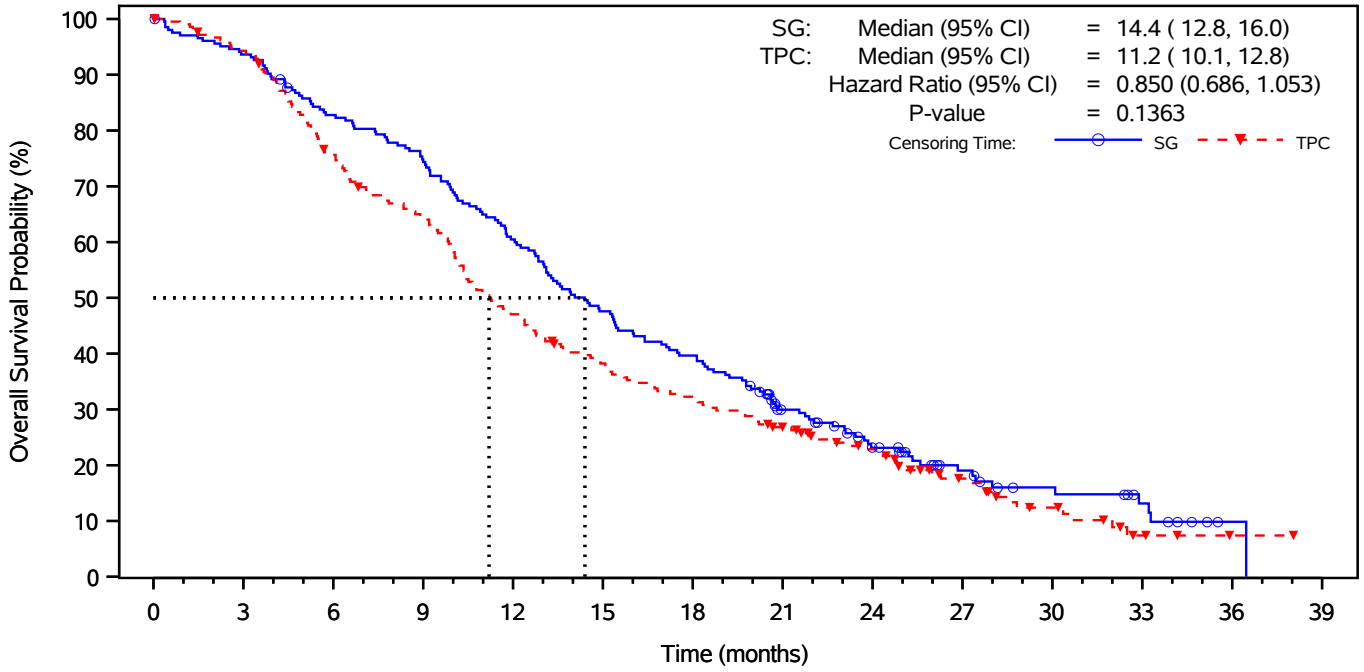
Figure 15.2.2.3: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	205 (0)	191 (13)	167 (35)	151 (51)	122 (80)	96 (106)	80 (122)	51 (141)	34 (152)	20 (157)	13 (160)	8 (162)	1 (164)	0 (165)
TPC	213 (0)	198 (12)	157 (51)	133 (74)	97 (110)	77 (128)	65 (140)	51 (151)	38 (158)	22 (166)	12 (172)	4 (176)	1 (176)	0 (176)

Final OS data cut is at 01Dec2022.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.2.2.1: Overall Survival (OS)
ITT Population

	SG (N = 272)	TPC (N = 271)	Treatment Comparison
Subjects with Events [n (%)]	214 (78.7%)	224 (82.7%)	
Subjects without Events (Censored) [n (%)]	58 (21.3%)	47 (17.3%)	
Median OS (95% CI) [a]	14.5 (13.0, 16.0)	11.2 (10.2, 12.6)	
Log-rank P-value (Stratified) [b]			0.0133
Stratified Cox Regression Analysis [b]			
Hazard Ratio (Relative to TPC)			0.788
95% CI for Hazard Ratio			(0.652, 0.952)
Kaplan-Meier Estimate of OS Rate (%) (95% CI) [c]			
At 12 Months	60.9 (54.8, 66.4)	47.1 (41.0, 53.0)	
At 18 Months	39.2 (33.4, 45.0)	31.7 (26.2, 37.4)	
At 24 Months	25.7 (20.5, 31.2)	21.1 (16.3, 26.3)	

OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause. Patients without documentation of death are censored on the date they were last known to be alive.
[a] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[b] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).
[c] OS rate is the proportion of subjects alive.

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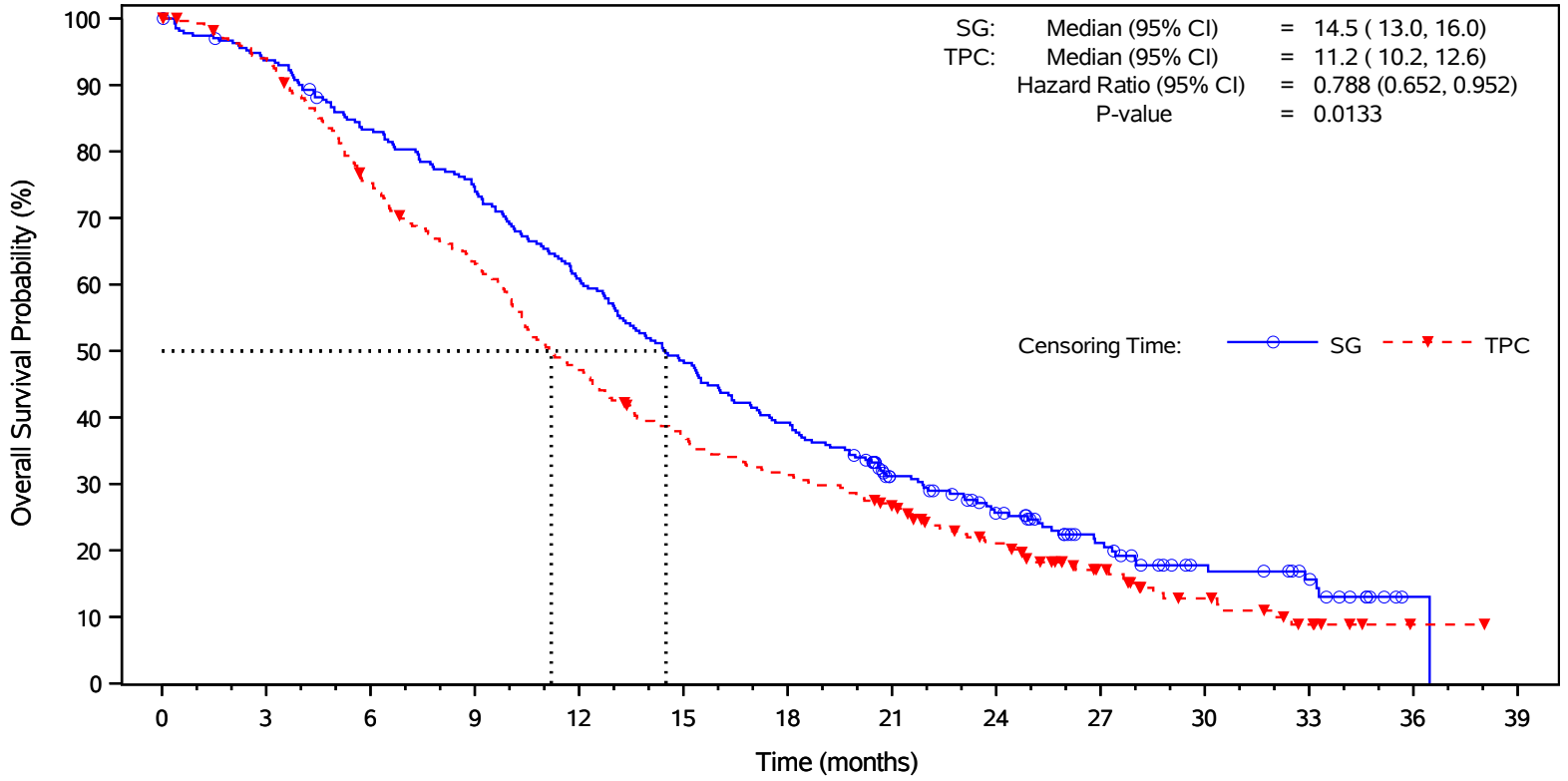
Figure 15.2.2.1: Kaplan-Meier Estimates of Overall Survival (OS)
ITT Population



No. of Patients Still at Risk (Events)

SG	272 (0)	253 (17)	223 (45)	200 (68)	163 (105)	130 (138)	105 (163)	71 (184)	52 (196)	33 (204)	19 (209)	13 (211)	1 (213)	0 (214)
TPC	271 (0)	251 (16)	199 (66)	167 (97)	124 (140)	96 (166)	82 (180)	66 (193)	46 (206)	27 (214)	15 (220)	7 (224)	1 (224)	0 (224)

Data Extracted: 22FEB2023. Data Cut Date: 01DEC2022.
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Table 15.2.2.6: Overall Survival (OS) by Pre-selected Gemcitabine vs non-Gemcitabine at Final OS Data
ITT Population

Subgroup/ Statistic	SG (N = 272)	TPC (N = 271)	Treatment Comparison
Interaction p-value [a]			0.3676
Pre-selected Gemcitabine			
Total Patients	67	58	
Patients (%) With Events	49 (73.1)	48 (82.8)	
Patients (%) Without Events (Censored)	18 (26.9)	10 (17.2)	
Median OS (months) [b]	15.5	11.1	
95% CI	(11.9, 17.6)	(8.2, 13.5)	
Hazard Ratio (Relative to TPC) [c]			0.692
95% CI for Hazard Ratio			(0.464, 1.032)
p-value			0.0697
Not pre-selected Gemcitabine			
Total Patients	205	213	
Patients (%) With Events	165 (80.5)	176 (82.6)	
Patients (%) Without Events (Censored)	40 (19.5)	37 (17.4)	
Median OS (months) [b]	14.4	11.2	
95% CI	(12.8, 16.0)	(10.1, 12.8)	
Hazard Ratio (Relative to TPC) [c]			0.835
95% CI for Hazard Ratio			(0.675, 1.033)
p-value			0.0971

The denominator is the number of patients in the ITT Population. Patients without documentation of death are censored on their last known alive date.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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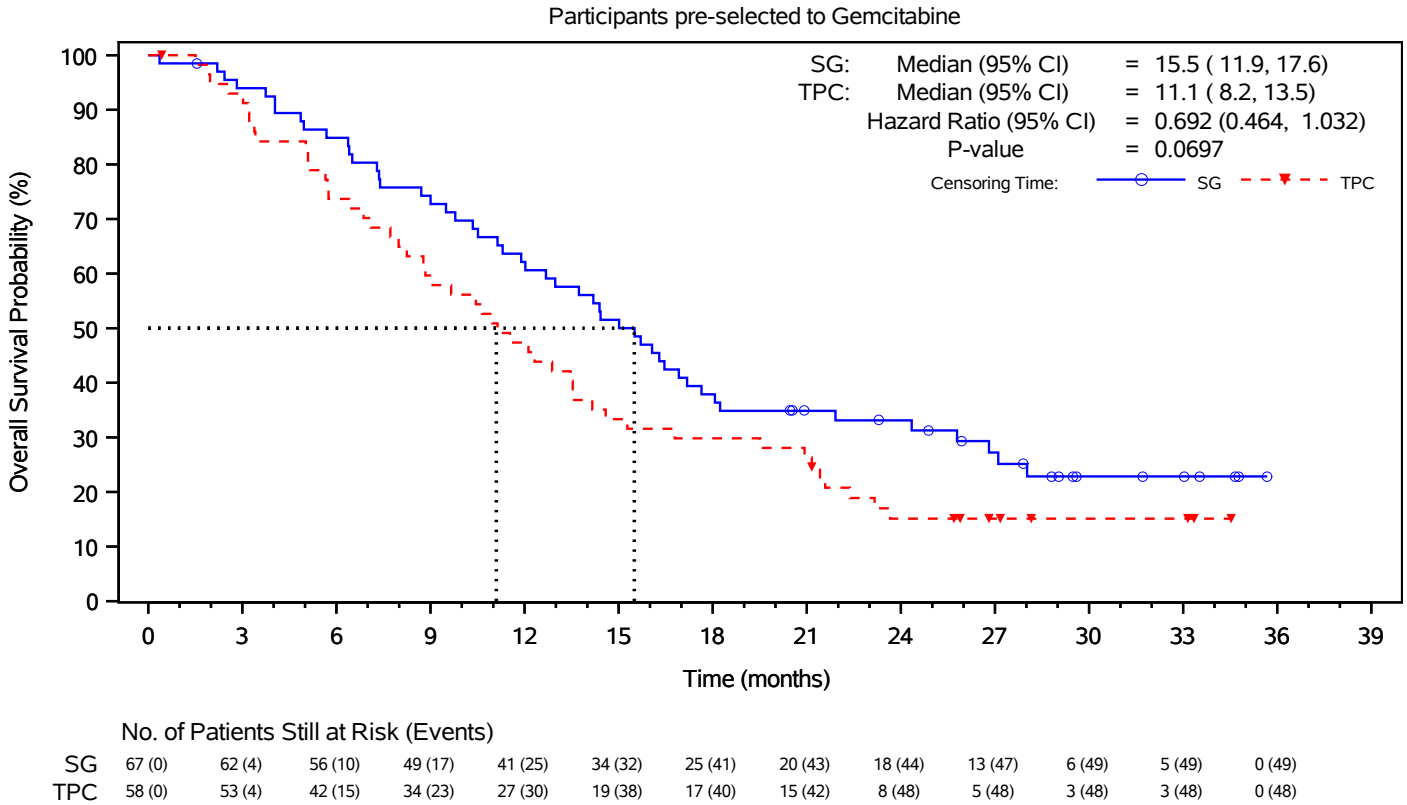
Figure 15.2.2.4.1: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Pre-selected Gemcitabine vs Non-Gemcitabine
ITT Population



Final OS data cut is at 01Dec2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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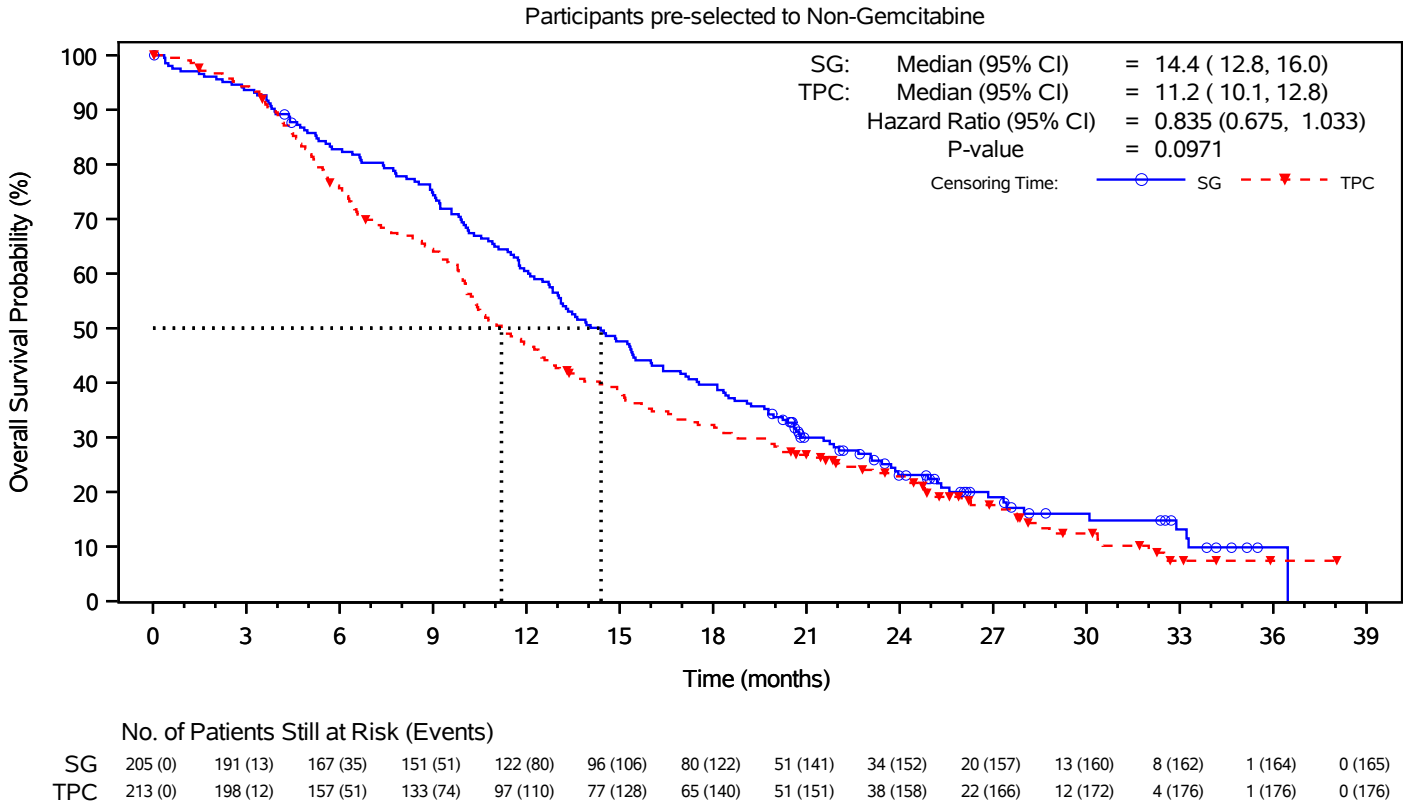
Figure 15.2.2.4.1: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Pre-selected Gemcitabine vs Non-Gemcitabine
ITT Population



Final OS data cut is at 01Dec2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Anhang 4-G 3.1: Subgruppenanalysen

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.6563
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	96	102	
Patients (%) With Events	75 (78.1%)	84 (82.4%)	
Patients (%) Without Events (Censored)	21 (21.9%)	18 (17.6%)	
Median OS (months) [b]	15.4	12.6	
95% CI	(12.5, 18.5)	(10.4, 15.8)	
Hazard Ratio (Relative to TPC) [c]			0.864
95% CI for Hazard Ratio			(0.632, 1.180)
p-value			0.3560
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	109	111	
Patients (%) With Events	90 (82.6%)	92 (82.9%)	
Patients (%) Without Events (Censored)	19 (17.4%)	19 (17.1%)	
Median OS (months) [b]	13.5	10.1	
95% CI	(11.8, 15.4)	(8.3, 12.4)	
Hazard Ratio (Relative to TPC) [c]			0.804
95% CI for Hazard Ratio			(0.601, 1.076)
p-value			0.1416

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.3186
Stratification factor of visceral metastasis: Yes			
Total Patients	196	205	
Patients (%) With Events	158 (80.6%)	171 (83.4%)	
Patients (%) Without Events (Censored)	38 (19.4%)	34 (16.6%)	
Median OS (months) [b]	14.6	10.8	
95% CI	(12.8, 16.4)	(10.0, 12.6)	
Hazard Ratio (Relative to TPC) [c]			0.819
95% CI for Hazard Ratio			(0.659, 1.017)
p-value			0.0696
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	7 (77.8%)	5 (62.5%)	
Patients (%) Without Events (Censored)	2 (22.2%)	3 (37.5%)	
Median OS (months) [b]	12.8	15.1	
95% CI	(4.4, NE)	(5.5, NE)	
Hazard Ratio (Relative to TPC) [c]			1.904
95% CI for Hazard Ratio			(0.597, 6.072)
p-value			0.2685

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.9512
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	183	185	
Patients (%) With Events	146 (79.8%)	150 (81.1%)	
Patients (%) Without Events (Censored)	37 (20.2%)	35 (18.9%)	
Median OS (months) [b]	14.6	11.8	
95% CI	(12.8, 17.2)	(10.4, 14.4)	
Hazard Ratio (Relative to TPC) [c]			0.846
95% CI for Hazard Ratio			(0.673, 1.064)
p-value			0.1514
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	22	28	
Patients (%) With Events	19 (86.4%)	26 (92.9%)	
Patients (%) Without Events (Censored)	3 (13.6%)	2 (7.1%)	
Median OS (months) [b]	10.8	8.3	
95% CI	(2.9, 15.4)	(4.6, 12.4)	
Hazard Ratio (Relative to TPC) [c]			0.830
95% CI for Hazard Ratio			(0.452, 1.526)
p-value			0.5483

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.7264
Age group: < 65 years			
Total Patients	158	161	
Patients (%) With Events	127 (80.4%)	133 (82.6%)	
Patients (%) Without Events (Censored)	31 (19.6%)	28 (17.4%)	
Median OS (months) [b]	13.6	11.8	
95% CI	(12.3, 16.4)	(10.3, 13.7)	
Hazard Ratio (Relative to TPC) [c]			0.849
95% CI for Hazard Ratio			(0.665, 1.083)
p-value			0.1875
Age group: >= 65 years			
Total Patients	47	52	
Patients (%) With Events	38 (80.9%)	43 (82.7%)	
Patients (%) Without Events (Censored)	9 (19.1%)	9 (17.3%)	
Median OS (months) [b]	14.9	10.1	
95% CI	(10.1, 19.6)	(6.6, 12.8)	
Hazard Ratio (Relative to TPC) [c]			0.791
95% CI for Hazard Ratio			(0.510, 1.228)
p-value			0.2980

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.9339
Race: White			
Total Patients	143	143	
Patients (%) With Events	114 (79.7%)	115 (80.4%)	
Patients (%) Without Events (Censored)	29 (20.3%)	28 (19.6%)	
Median OS (months) [b]	14.4	12.2	
95% CI	(12.1, 17.2)	(10.4, 13.6)	
Hazard Ratio (Relative to TPC) [c]			0.882
95% CI for Hazard Ratio			(0.680, 1.143)
p-value			0.3428
Race: Non-white			
Total Patients	14	18	
Patients (%) With Events	12 (85.7%)	14 (77.8%)	
Patients (%) Without Events (Censored)	2 (14.3%)	4 (22.2%)	
Median OS (months) [b]	13.8	10.5	
95% CI	(7.8, 20.6)	(3.7, 24.3)	
Hazard Ratio (Relative to TPC) [c]			0.870
95% CI for Hazard Ratio			(0.396, 1.911)
p-value			0.7278

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.7942
Screening ECOG Status: 0			
Total Patients	90	99	
Patients (%) With Events	68 (75.6%)	73 (73.7%)	
Patients (%) Without Events (Censored)	22 (24.4%)	26 (26.3%)	
Median OS (months) [b]	18.1	14.6	
95% CI	(12.8, 20.7)	(10.2, 19.7)	
Hazard Ratio (Relative to TPC) [c]			0.836
95% CI for Hazard Ratio			(0.599, 1.167)
p-value			0.2939
Screening ECOG Status: 1			
Total Patients	115	114	
Patients (%) With Events	97 (84.3%)	103 (90.4%)	
Patients (%) Without Events (Censored)	18 (15.7%)	11 (9.6%)	
Median OS (months) [b]	13.1	10.4	
95% CI	(11.0, 15.2)	(8.7, 11.8)	
Hazard Ratio (Relative to TPC) [c]			0.800
95% CI for Hazard Ratio			(0.606, 1.056)
p-value			0.1148

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.1728
Geographic Region: Europe			
Total Patients	125	130	
Patients (%) With Events	97 (77.6%)	110 (84.6%)	
Patients (%) Without Events (Censored)	28 (22.4%)	20 (15.4%)	
Median OS (months) [b]	15.3	11.5	
95% CI	(12.8, 18.3)	(9.8, 13.6)	
Hazard Ratio (Relative to TPC) [c]			0.739
95% CI for Hazard Ratio			(0.562, 0.972)
p-value			0.0301
Geographic Region: North America			
Total Patients	80	83	
Patients (%) With Events	68 (85.0%)	66 (79.5%)	
Patients (%) Without Events (Censored)	12 (15.0%)	17 (20.5%)	
Median OS (months) [b]	13.5	11.0	
95% CI	(10.8, 15.4)	(9.9, 13.7)	
Hazard Ratio (Relative to TPC) [c]			0.999
95% CI for Hazard Ratio			(0.711, 1.404)
p-value			0.9948

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.1301
Prior CDK treatment duration: <= 12 months			
Total Patients	118	128	
Patients (%) With Events	95 (80.5%)	110 (85.9%)	
Patients (%) Without Events (Censored)	23 (19.5%)	18 (14.1%)	
Median OS (months) [b]	14.4	10.5	
95% CI	(12.7, 17.0)	(9.8, 12.4)	
Hazard Ratio (Relative to TPC) [c]			0.708
95% CI for Hazard Ratio			(0.537, 0.934)
p-value			0.0140
Prior CDK treatment duration: > 12 months			
Total Patients	82	82	
Patients (%) With Events	66 (80.5%)	64 (78.0%)	
Patients (%) Without Events (Censored)	16 (19.5%)	18 (22.0%)	
Median OS (months) [b]	14.5	12.7	
95% CI	(11.8, 18.1)	(10.0, 18.0)	
Hazard Ratio (Relative to TPC) [c]			0.997
95% CI for Hazard Ratio			(0.706, 1.409)
p-value			0.9862

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.5692
Early relapse: Yes			
Total Patients	13	17	
Patients (%) With Events	11 (84.6%)	15 (88.2%)	
Patients (%) Without Events (Censored)	2 (15.4%)	2 (11.8%)	
Median OS (months) [b]	12.8	9.9	
95% CI	(6.7, 18.4)	(3.4, 15.8)	
Hazard Ratio (Relative to TPC) [c]			0.671
95% CI for Hazard Ratio			(0.300, 1.501)
p-value			0.3286
Early relapse: No			
Total Patients	185	192	
Patients (%) With Events	149 (80.5%)	159 (82.8%)	
Patients (%) Without Events (Censored)	36 (19.5%)	33 (17.2%)	
Median OS (months) [b]	14.5	11.3	
95% CI	(12.7, 16.4)	(10.1, 13.3)	
Hazard Ratio (Relative to TPC) [c]			0.855
95% CI for Hazard Ratio			(0.683, 1.069)
p-value			0.1694

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.3292
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	181	187	
Patients (%) With Events	149 (82.3%)	156 (83.4%)	
Patients (%) Without Events (Censored)	32 (17.7%)	31 (16.6%)	
Median OS (months) [b]	13.9	11.0	
95% CI	(12.3, 15.5)	(10.0, 12.8)	
Hazard Ratio (Relative to TPC) [c]			0.871
95% CI for Hazard Ratio			(0.696, 1.091)
p-value			0.2290
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	26	
Patients (%) With Events	16 (66.7%)	20 (76.9%)	
Patients (%) Without Events (Censored)	8 (33.3%)	6 (23.1%)	
Median OS (months) [b]	18.4	12.5	
95% CI	(11.9, NE)	(9.5, 15.3)	
Hazard Ratio (Relative to TPC) [c]			0.603
95% CI for Hazard Ratio			(0.307, 1.183)
p-value			0.1370

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.5788
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	125	145	
Patients (%) With Events	101 (80.8%)	119 (82.1%)	
Patients (%) Without Events (Censored)	24 (19.2%)	26 (17.9%)	
Median OS (months) [b]	14.3	10.6	
95% CI	(12.5, 17.0)	(9.9, 12.4)	
Hazard Ratio (Relative to TPC) [c]			0.795
95% CI for Hazard Ratio			(0.609, 1.037)
p-value			0.0891
Chemotherapy in neo/adjuvant setting: No			
Total Patients	80	68	
Patients (%) With Events	64 (80.0%)	57 (83.8%)	
Patients (%) Without Events (Censored)	16 (20.0%)	11 (16.2%)	
Median OS (months) [b]	14.4	13.6	
95% CI	(11.1, 18.1)	(9.2, 17.2)	
Hazard Ratio (Relative to TPC) [c]			0.925
95% CI for Hazard Ratio			(0.647, 1.323)
p-value			0.6703

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.6648
Trop2: H-Score < 100			
Total Patients	68	73	
Patients (%) With Events	57 (83.8%)	62 (84.9%)	
Patients (%) Without Events (Censored)	11 (16.2%)	11 (15.1%)	
Median OS (months) [b]	14.1	12.4	
95% CI	(11.8, 19.1)	(10.1, 13.9)	
Hazard Ratio (Relative to TPC) [c]			0.904
95% CI for Hazard Ratio			(0.630, 1.298)
p-value			0.5801
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	78	
Patients (%) With Events	59 (83.1%)	66 (84.6%)	
Patients (%) Without Events (Censored)	12 (16.9%)	12 (15.4%)	
Median OS (months) [b]	13.6	10.3	
95% CI	(10.8, 16.0)	(7.9, 11.8)	
Hazard Ratio (Relative to TPC) [c]			0.771
95% CI for Hazard Ratio			(0.541, 1.098)
p-value			0.1501

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Trop2: H-Score > 200			
Total Patients	42	26	
Patients (%) With Events	31 (73.8%)	17 (65.4%)	
Patients (%) Without Events (Censored)	11 (26.2%)	9 (34.6%)	
Median OS (months) [b]	17.2	14.6	
95% CI	(11.8, 22.7)	(9.9, NE)	
Hazard Ratio (Relative to TPC) [c]			1.072
95% CI for Hazard Ratio			(0.590, 1.947)
p-value			0.8180

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.0408
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	19 (90.5%)	16 (69.6%)	
Patients (%) Without Events (Censored)	2 (9.5%)	7 (30.4%)	
Median OS (months) [b]	16.4	20.1	
95% CI	(11.4, 22.0)	(10.1, 30.4)	
Hazard Ratio (Relative to TPC) [c]			1.364
95% CI for Hazard Ratio			(0.694, 2.682)
p-value			0.3656
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	128	130	
Patients (%) With Events	100 (78.1%)	105 (80.8%)	
Patients (%) Without Events (Censored)	28 (21.9%)	25 (19.2%)	
Median OS (months) [b]	15.3	11.7	
95% CI	(12.7, 19.2)	(10.1, 13.9)	
Hazard Ratio (Relative to TPC) [c]			0.842
95% CI for Hazard Ratio			(0.640, 1.108)
p-value			0.2187

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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Table 15.2.2.3: Overall Survival (OS) by Selected Subgroup at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	56	60	
Patients (%) With Events	46 (82.1%)	55 (91.7%)	
Patients (%) Without Events (Censored)	10 (17.9%)	5 (8.3%)	
Median OS (months) [b]	12.9	8.3	
95% CI	(9.6, 14.4)	(6.3, 11.3)	
Hazard Ratio (Relative to TPC) [c]			0.642
95% CI for Hazard Ratio			(0.433, 0.950)
p-value			0.0254

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Final OS data cut is at 12/1/2022.

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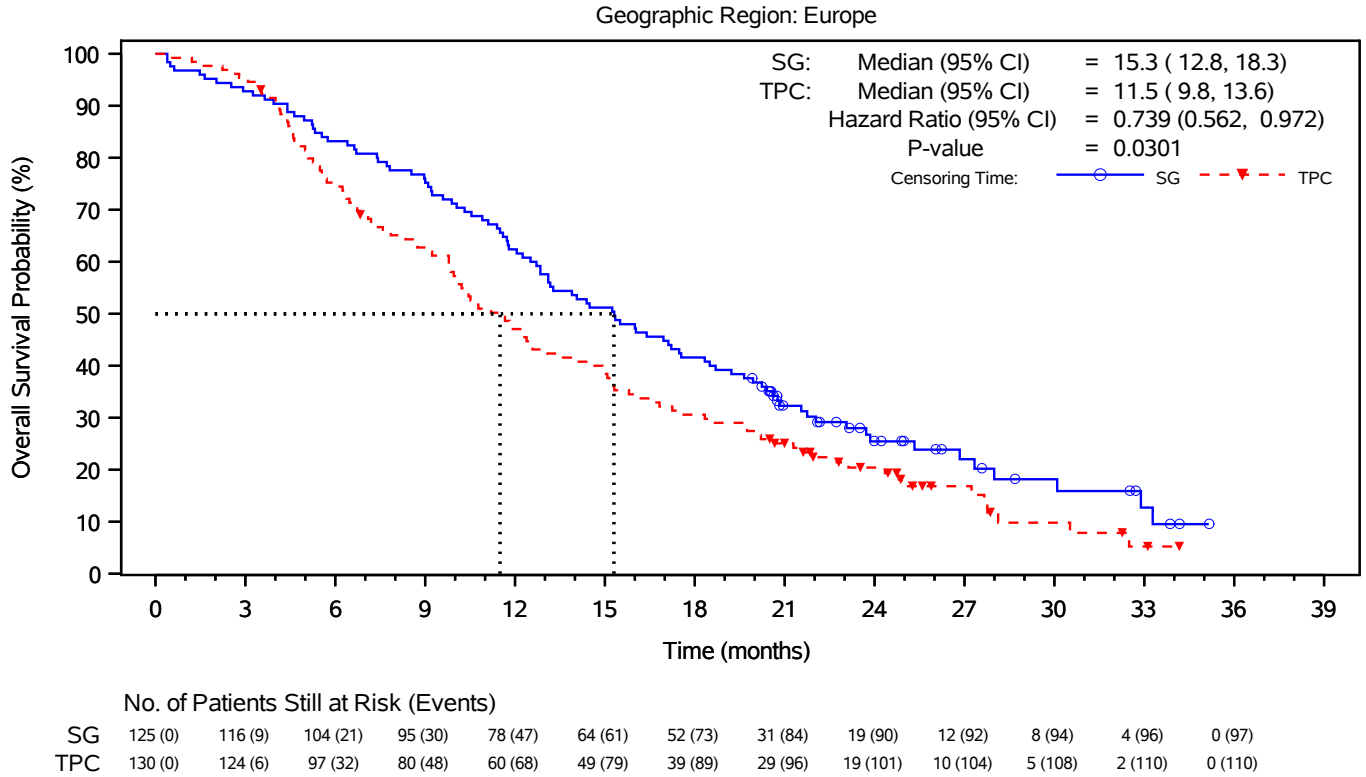
Figure 15.2.2.5.7: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Geographic Region
ITT Population
Excluding Participants Pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	125 (0)	116 (9)	104 (21)	95 (30)	78 (47)	64 (61)	52 (73)	31 (84)	19 (90)	12 (92)	8 (94)	4 (96)	0 (97)
TPC	130 (0)	124 (6)	97 (32)	80 (48)	60 (68)	49 (79)	39 (89)	29 (96)	19 (101)	10 (104)	5 (108)	2 (110)	0 (110)

Final OS data cut is at 01Dec2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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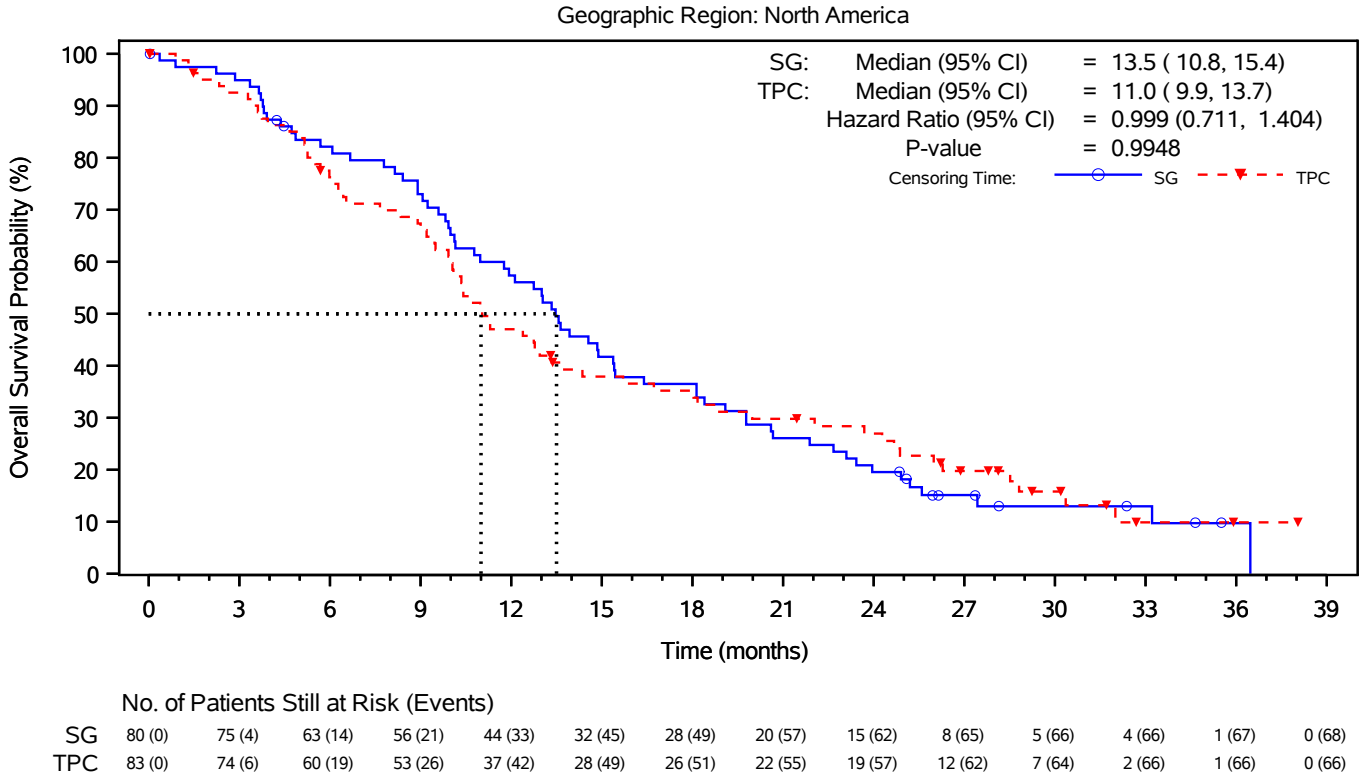
Figure 15.2.2.5.7: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Geographic Region
ITT Population
Excluding Participants Pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	80 (0)	75 (4)	63 (14)	56 (21)	44 (33)	32 (45)	28 (49)	20 (57)	15 (62)	8 (65)	5 (66)	4 (66)	1 (67)	0 (68)
TPC	83 (0)	74 (6)	60 (19)	53 (26)	37 (42)	28 (49)	26 (51)	22 (55)	19 (57)	12 (62)	7 (64)	2 (66)	1 (66)	0 (66)

Final OS data cut is at 01Dec2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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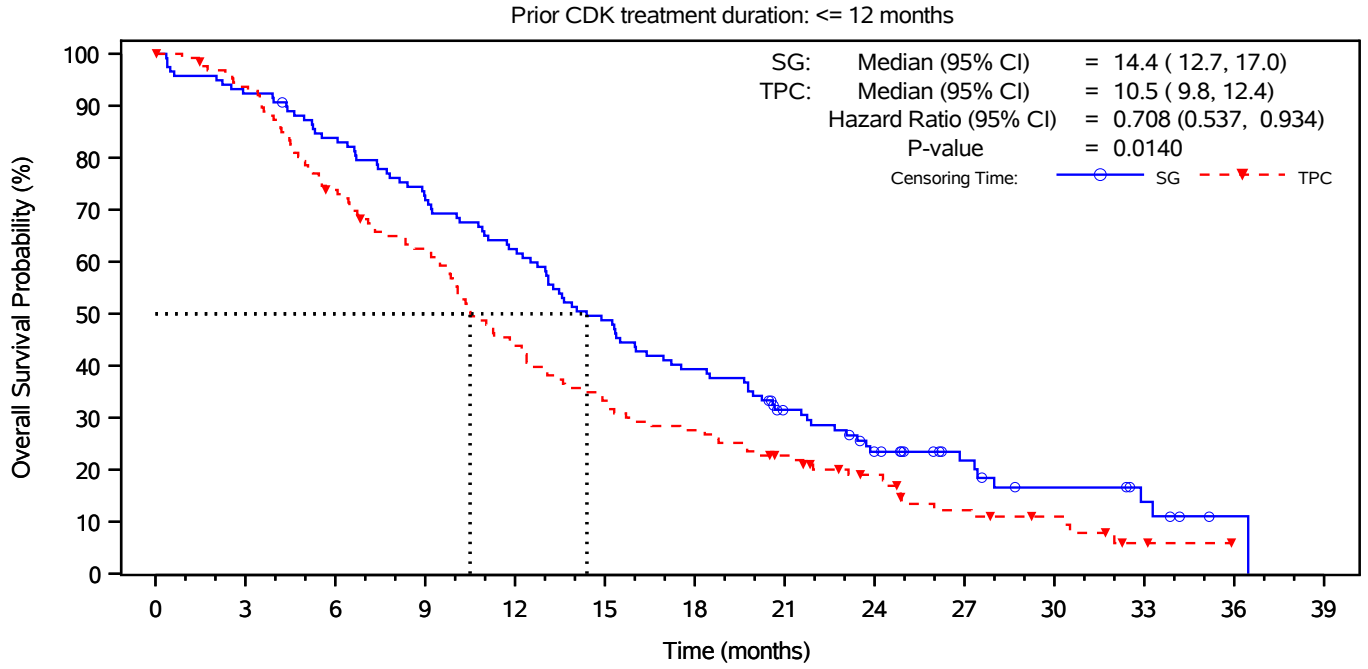
Figure 15.2.2.5.8: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Prior CDK Treatment Duration
ITT Population
Excluding Participants Pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	118 (0)	109 (9)	98 (19)	85 (32)	73 (44)	57 (60)	46 (71)	32 (80)	21 (88)	13 (89)	8 (92)	5 (93)	1 (94)	0 (95)
TPC	128 (0)	118 (8)	92 (33)	77 (47)	54 (70)	41 (83)	34 (90)	26 (96)	18 (100)	10 (106)	7 (107)	2 (110)	0 (110)	

Final OS data cut is at 01Dec2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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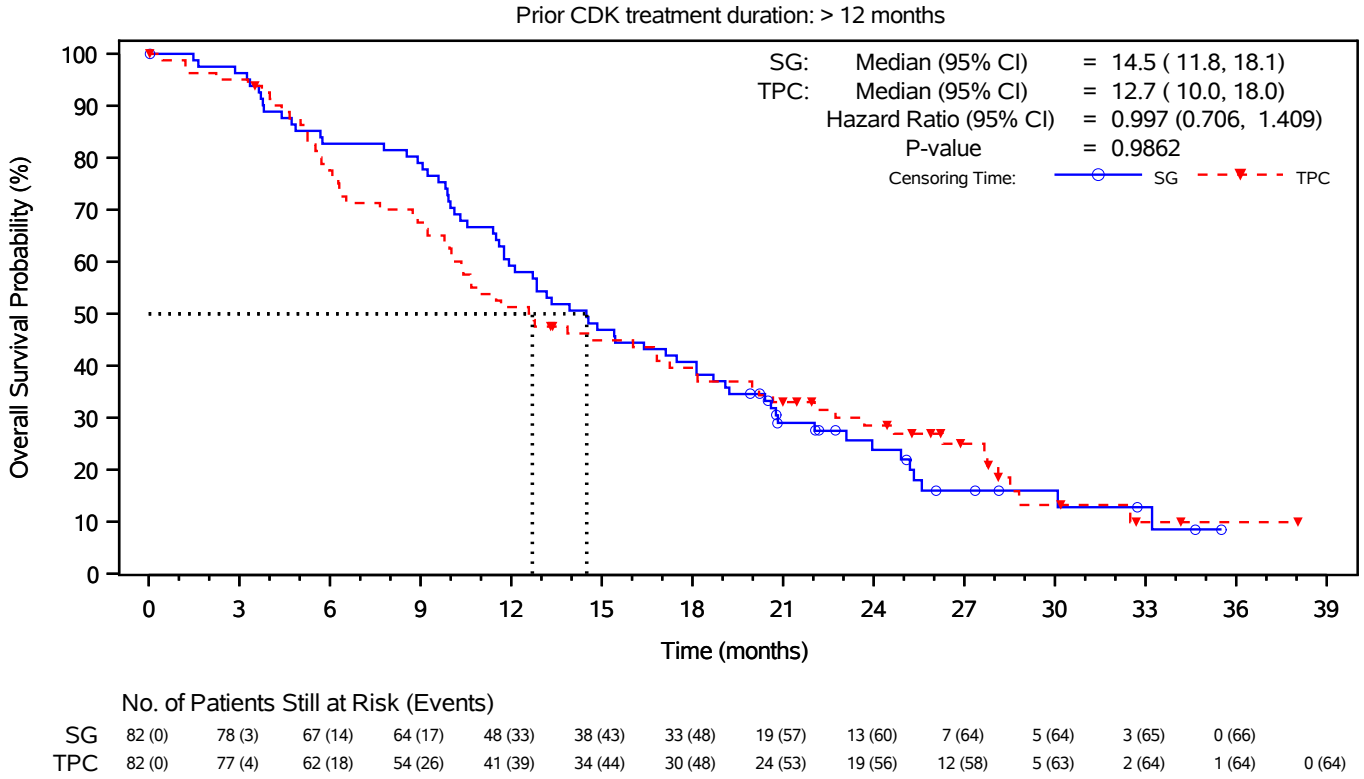
Figure 15.2.2.5.8: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Prior CDK Treatment Duration
ITT Population
Excluding Participants Pre-selected to Gemcitabine



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Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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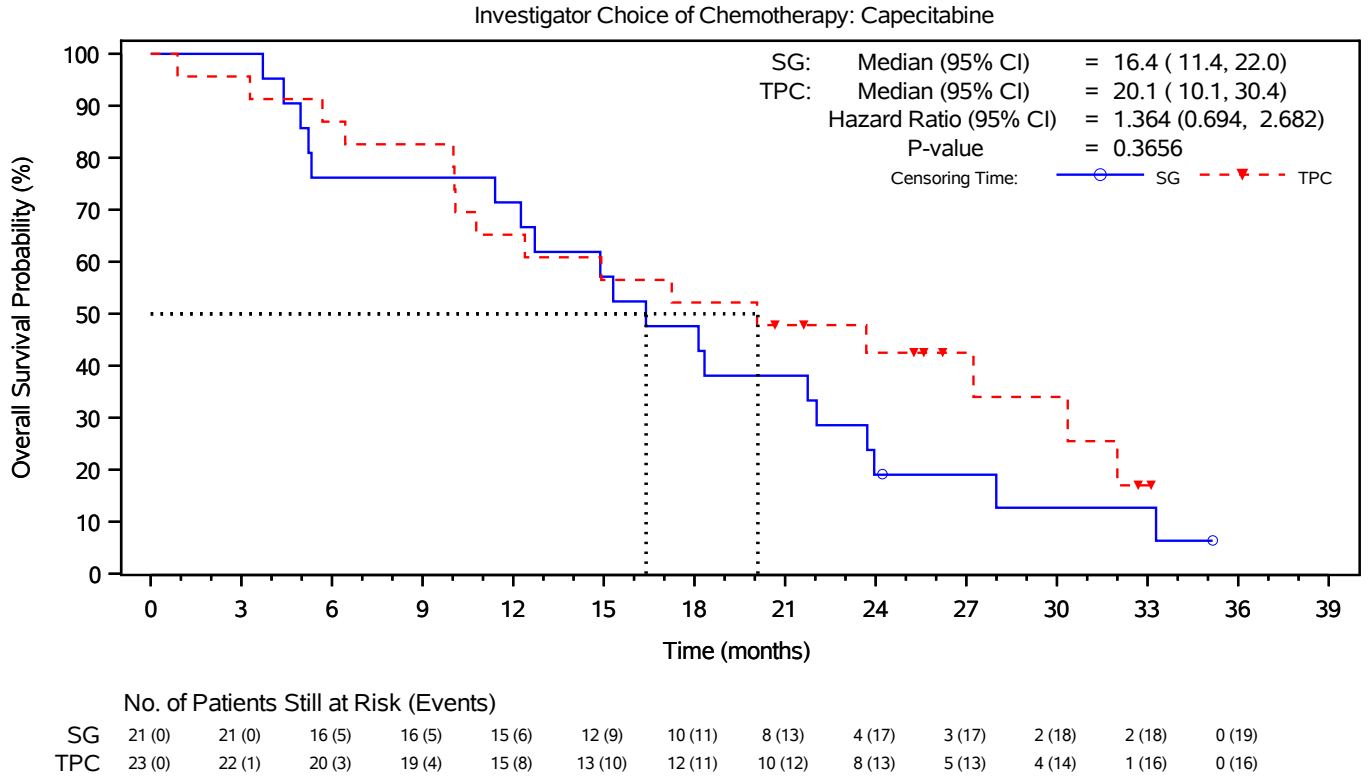
Figure 15.2.2.5.13: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Investigator Choice of Chemotherapy Prior to Randomization
ITT Population
Excluding Participants Pre-selected to Gemcitabine



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Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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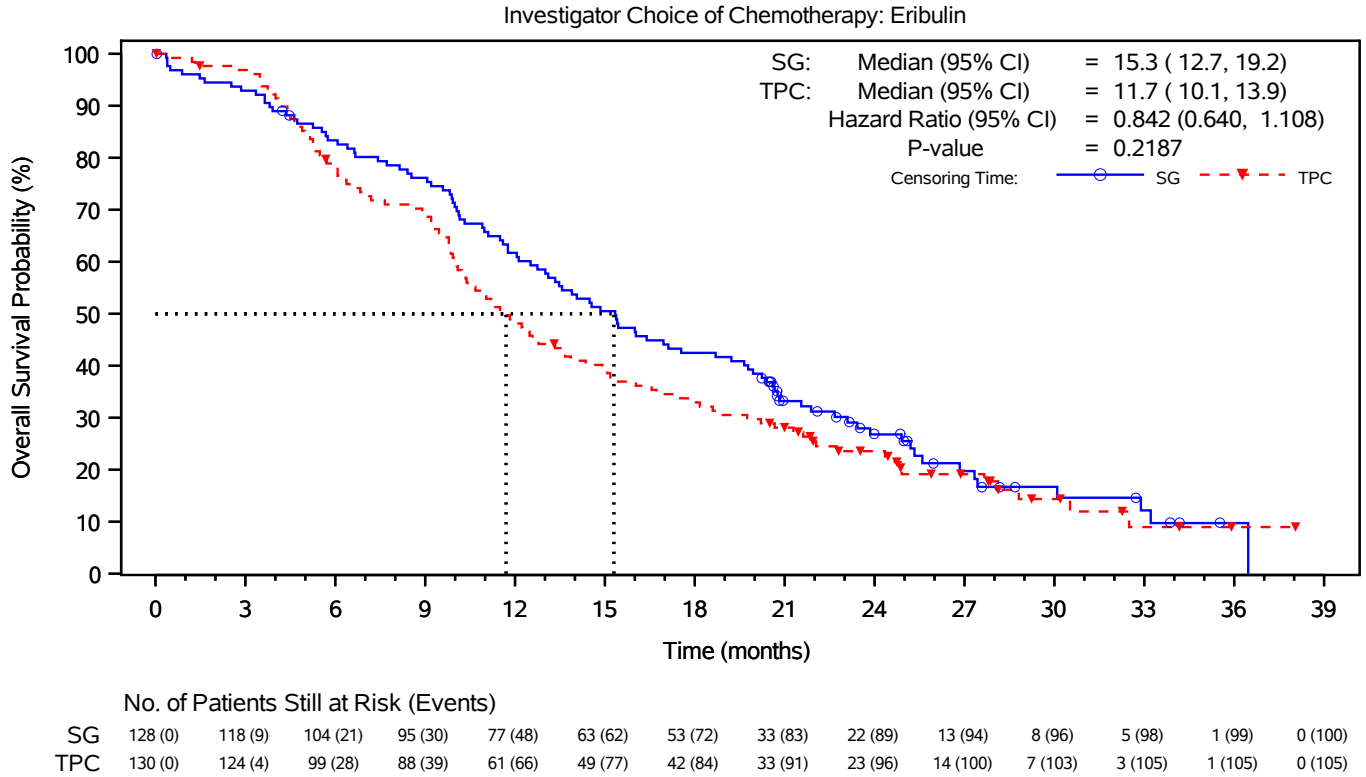
Figure 15.2.2.5.13: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Investigator Choice of Chemotherapy Prior to Randomization
ITT Population
Excluding Participants Pre-selected to Gemcitabine



Final OS data cut is at 01Dec2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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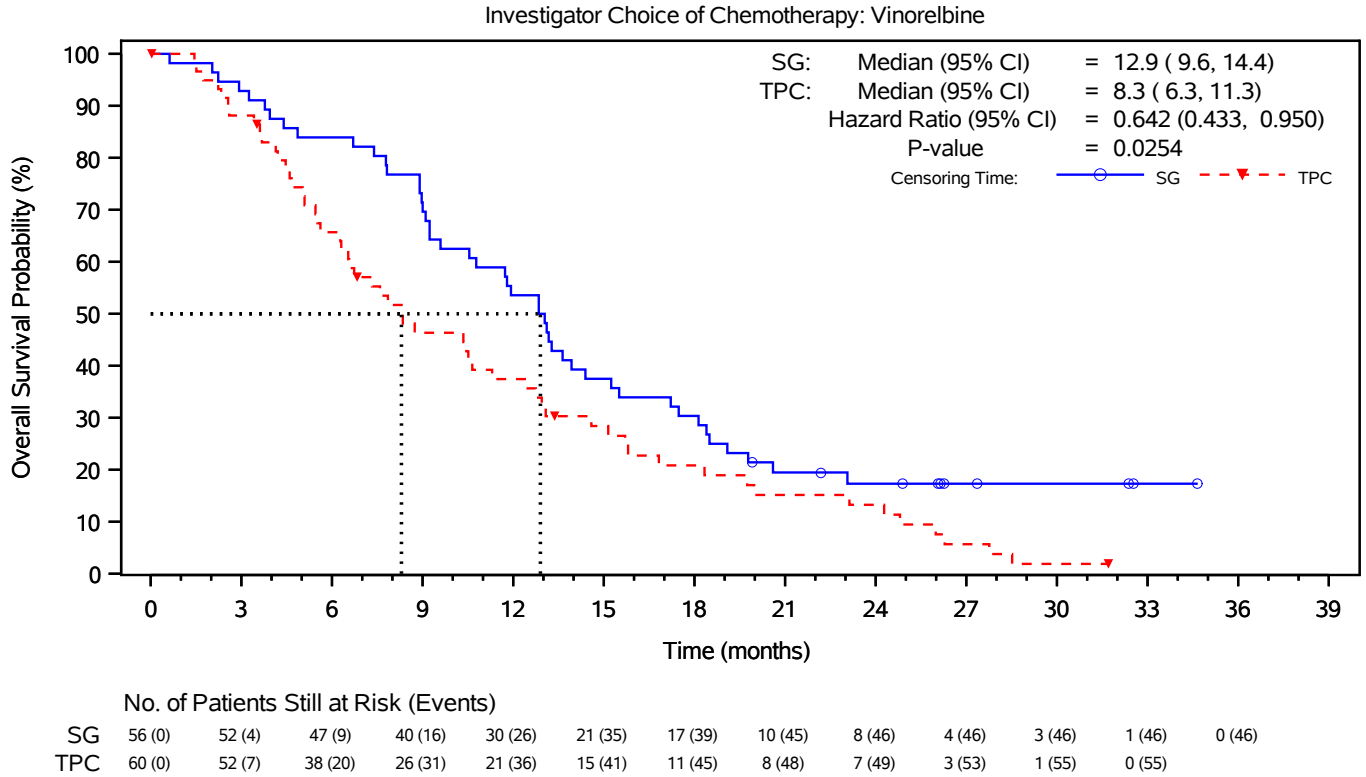
Figure 15.2.2.5.13: Kaplan-Meier Estimates of Overall Survival (OS) at Final OS Data by Investigator Choice of Chemotherapy Prior to Randomization
ITT Population
Excluding Participants Pre-selected to Gemcitabine



Final OS data cut is at 01Dec2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.2.10: Overall Survival (OS) by CDK4/6 Duration (<6 vs >=6 months) at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

Subgroup/ Statistic	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Prior CDK treatment duration: <6 months			
Total Subjects	62	66	
OS Events [n (%)]	47 (75.8%)	59 (89.4%)	
Censored [n (%)]	15 (24.2%)	7 (10.6%)	
Median OS (months) [a]	15.3	10.4	
95% CI	(13.0, 19.8)	(9.0, 13.3)	
Hazard Ratio (Relative to TPC) [b]			0.634
95% CI for Hazard Ratio			(0.432, 0.932)
p-value			0.0195
Prior CDK treatment duration: >=6 months			
Total Subjects	138	144	
OS Events [n (%)]	114 (82.6%)	115 (79.9%)	
Censored [n (%)]	24 (17.4%)	29 (20.1%)	
Median OS (months) [a]	13.9	11.2	
95% CI	(12.1, 16.4)	(10.1, 13.9)	
Hazard Ratio (Relative to TPC) [b]			0.925
95% CI for Hazard Ratio			(0.713, 1.199)
p-value			0.5543

The denominator is the number of patients in the ITT Population excluding those assigned to Gemcitabine before randomized for each treatment group.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[b] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Prior CDK4/6 treatment duration calculated based on the total duration, defined as the sum of consecutive use of CDK4/6.
Final OS data cut is at 01Dec2022.

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Table 15.2.2.11: Overall Survival (OS) by CDK4/6 Duration (<18 vs >=18 months) at Final OS Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

Subgroup/ Statistic	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Prior CDK treatment duration: <18 months			
Total Subjects	153	165	
OS Events [n (%)]	122 (79.7%)	139 (84.2%)	
Censored [n (%)]	31 (20.3%)	26 (15.8%)	
Median OS (months) [a]	14.5	10.5	
95% CI	(12.8, 17.0)	(9.9, 12.3)	
Hazard Ratio (Relative to TPC) [b]			0.714
95% CI for Hazard Ratio			(0.559, 0.912)
p-value			0.0067
Prior CDK treatment duration: >=18 months			
Total Subjects	47	45	
OS Events [n (%)]	39 (83.0%)	35 (77.8%)	
Censored [n (%)]	8 (17.0%)	10 (22.2%)	
Median OS (months) [a]	14.2	16.7	
95% CI	(10.3, 19.2)	(6.5, 24.7)	
Hazard Ratio (Relative to TPC) [b]			1.233
95% CI for Hazard Ratio			(0.778, 1.954)
p-value			0.3719

The denominator is the number of patients in the ITT Population excluding those assigned to Gemcitabine before randomized for each treatment group.
OS is defined as the number of months (30.4375 days) from date of randomization to the date of death from any cause.
Patients without documentation of death are censored on the date they were last known to be alive.
[a] Median OS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[b] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Prior CDK4/6 treatment duration calculated based on the total duration, defined as the sum of consecutive use of CDK4/6.
Final OS data cut is at 01Dec2022.

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Anhang 4-G 4: Progressionsfreies Überleben

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Table 15.2.1.1: Progression Free Survival (PFS) per Blinded Independent Central Review (BICR) for Interim Analysis 1 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
PFS Events [n (%)]	131 (63.9%)	133 (62.4%)	
Disease Progression	110 (53.7%)	118 (55.4%)	
Death	21 (10.2%)	15 (7.0%)	
Censored [n (%)]	74 (36.1%)	80 (37.6%)	
Death after Starting New Anti-cancer Therapy	26 (12.7%)	20 (9.4%)	
Death after 2 or More Consecutive Missing Visits	3 (1.5%)	2 (0.9%)	
No PD and No Death	37 (18.0%)	27 (12.7%)	
No Baseline Image or Postbaseline Evaluable Assessment [a]	8 (3.9%)	31 (14.6%)	
Median PFS (95% CI) [b]	5.3 (4.1, 6.7)	4.0 (3.0, 4.4)	
Log-rank P-value (Stratified) [c]			0.0030
Stratified Cox Regression Analysis [c]			
Hazard Ratio (Relative to TPC)			0.687
95% CI for Hazard Ratio			(0.536, 0.881)
Kaplan-Meier Estimate of PFS Rate (%) (95% CI) [d]			
At 6 Months	44.2 (36.6, 51.6)	27.9 (20.8, 35.4)	
At 9 Months	27.7 (20.5, 35.4)	16.6 (10.6, 23.8)	
At 12 Months	22.0 (15.1, 29.8)	7.0 (2.7, 14.0)	

PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 1 has data cut at 1/3/2022.
[a] Censoring due to no baseline or no post baseline evaluable assessment does not include death event before the 2nd scheduled visit postbaseline.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).

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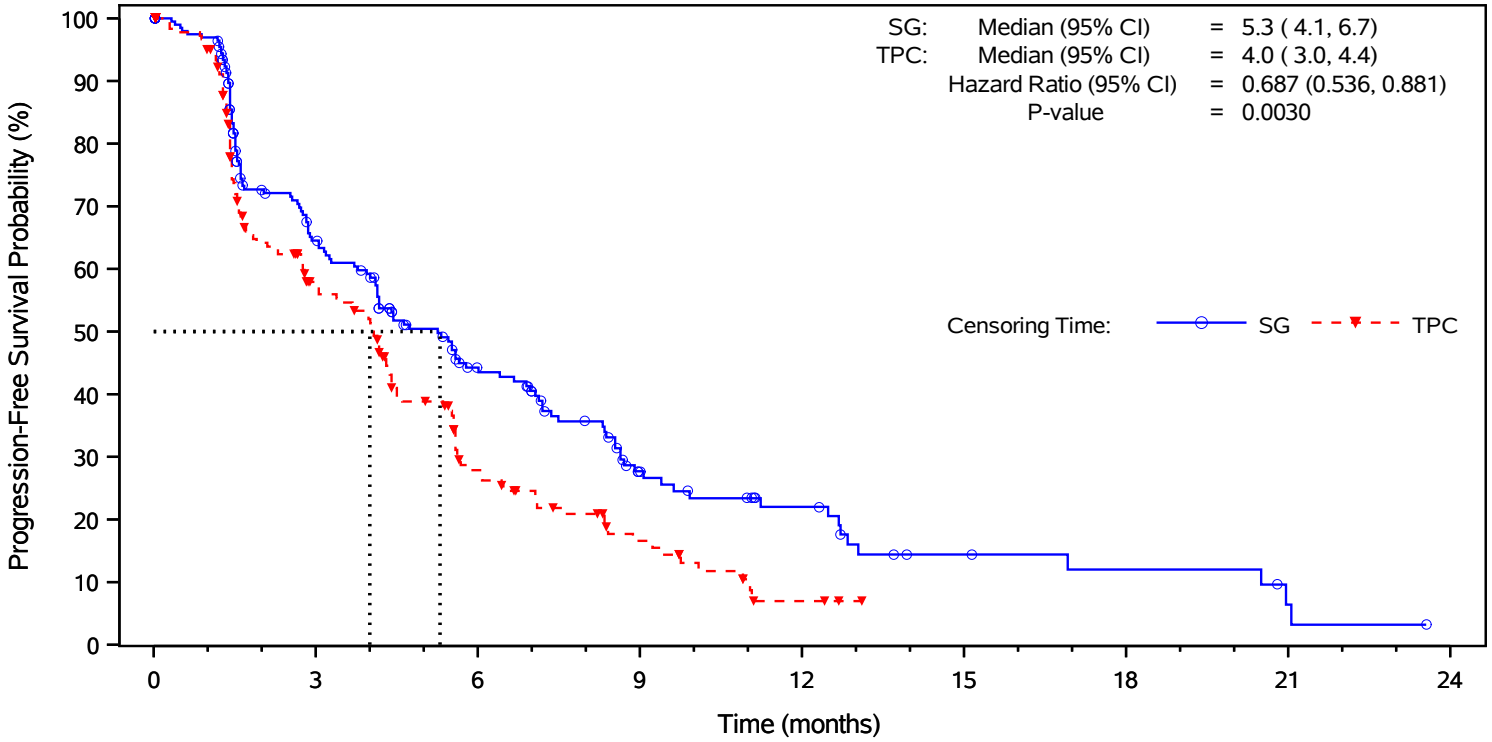
Gilead Sciences, Inc.
Study IMMU-132-09

Figure 15.2.1.1: Kaplan-Meier Estimates of Progression Free Survival (PFS) per BICR for Interim Analysis 1 Data
ITT Population
Excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	205 (0)	110 (65)	60 (97)	27 (117)	16 (122)	7 (127)	5 (128)	2 (130)	0 (131)
TPC	213 (0)	88 (72)	34 (114)	15 (126)	3 (133)	0 (133)			

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Gilead Sciences, Inc.
Study IMMU-132-09

Table 15.2.1.4: Progression Free Survival (PFS) per Blinded Independent Central Review (BICR) for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
PFS Events [n (%)]	135 (65.9%)	142 (66.7%)	
Disease Progression	112 (54.6%)	120 (56.3%)	
Death	23 (11.2%)	22 (10.3%)	
Censored [n (%)]	70 (34.1%)	71 (33.3%)	
Death after Starting New Anti-cancer Therapy	28 (13.7%)	24 (11.3%)	
Death after 2 or More Consecutive Missing Visits	9 (4.4%)	20 (9.4%)	
No PD and No Death	30 (14.6%)	17 (8.0%)	
No Baseline Image or Postbaseline Evaluable Assessment [a]	3 (1.5%)	10 (4.7%)	
Median PFS (95% CI) [b]	4.7 (4.1, 6.4)	4.0 (2.8, 4.4)	
Log-rank P-value (Stratified) [c]			0.0014
Stratified Cox Regression Analysis [c]			
Hazard Ratio (Relative to TPC)			0.673
95% CI for Hazard Ratio			(0.528, 0.859)
Kaplan-Meier Estimate of PFS Rate (%) (95% CI) [d]			
At 6 Months	43.8 (36.2, 51.1)	27.3 (20.4, 34.6)	
At 9 Months	27.6 (20.5, 35.2)	15.9 (10.2, 22.8)	
At 12 Months	22.0 (15.4, 29.5)	8.3 (4.0, 14.6)	

PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Censoring due to no baseline or no post baseline evaluable assessment does not include death event before the 2nd scheduled visit postbaseline.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).

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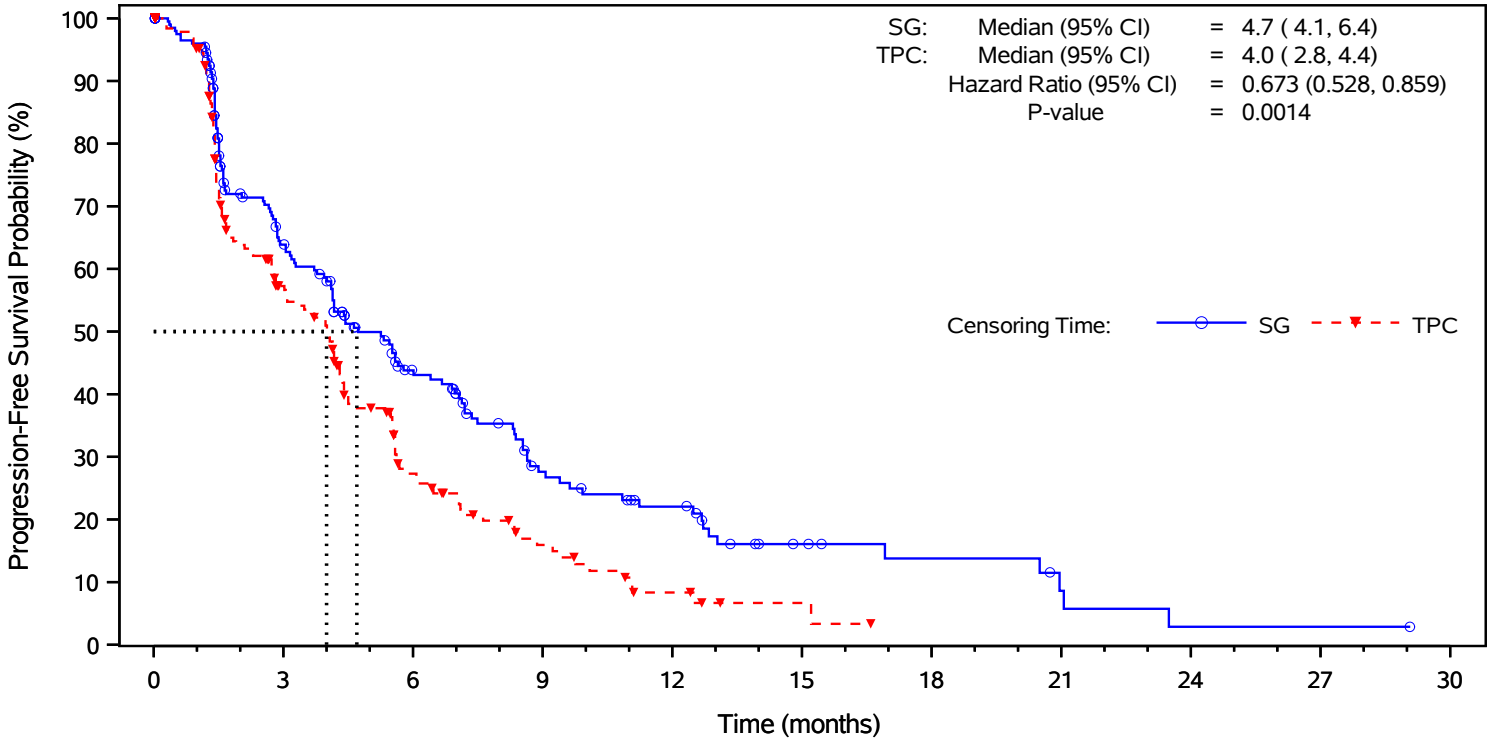
Figure 15.2.1.3: Kaplan-Meier Estimates of Progression Free Survival (PFS) per BICR for Interim Analysis 2 Data
ITT Population
Excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	205 (0)	110 (67)	60 (99)	31 (119)	21 (125)	9 (130)	6 (131)	3 (133)	1 (135)	1 (135)	0 (135)
TPC	213 (0)	91 (76)	35 (120)	16 (133)	6 (140)	2 (141)	0 (142)				

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Table 15.2.1.9: Progression Free Survival (PFS) per Local Investigator Review (LIR) for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
PFS Events [n (%)]	176 (85.9%)	167 (78.4%)	
Disease Progression	161 (78.5%)	152 (71.4%)	
Death	15 (7.3%)	15 (7.0%)	
Censored [n (%)]	29 (14.1%)	46 (21.6%)	
PD after Starting New Anti-cancer Therapy	0 (0.0%)	1 (0.5%)	
Death after Starting New Anti-cancer Therapy	10 (4.9%)	11 (5.2%)	
Death after 2 or More Consecutive Missing Visits	5 (2.4%)	18 (8.5%)	
No PD and No Death	11 (5.4%)	6 (2.8%)	
No Baseline Image or Postbaseline Evaluable Assessment [a]	3 (1.5%)	10 (4.7%)	
Median PFS (95% CI) [b]	4.4 (4.0, 5.4)	3.3 (2.7, 4.1)	
Log-rank P-value (Stratified) [c]			0.0192
Stratified Cox Regression Analysis [c]			
Hazard Ratio (Relative to TPC)			0.773
95% CI for Hazard Ratio			(0.622, 0.961)
Kaplan-Meier Estimate of PFS Rate (%) (95% CI) [d]			
At 3 Months	62.3 (55.1, 68.7)	53.3 (45.8, 60.2)	
At 6 Months	33.9 (27.2, 40.7)	25.0 (18.7, 31.7)	
At 9 Months	17.8 (12.6, 23.7)	12.5 (7.9, 18.1)	
At 12 Months	11.9 (7.6, 17.1)	5.9 (2.8, 10.5)	
At 18 Months	6.3 (3.2, 10.8)	NE (NE, NE)	

PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Censoring due to no baseline or no post baseline evaluable assessment does not include death event before the 2nd scheduled visit postbaseline.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).

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Anhang 4-G 4.1: Subgruppenanalysen

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.6916
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	96	102	
Patients (%) With Events	67 (69.8%)	73 (71.6%)	
Patients (%) Without Events (Censored)	29 (30.2%)	29 (28.4%)	
Median PFS (months) [b]	5.5	4.0	
95% CI	(4.1, 7.5)	(2.7, 4.6)	
Hazard Ratio (Relative to TPC) [c]			0.633
95% CI for Hazard Ratio			(0.452, 0.886)
p-value			0.0073
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	109	111	
Patients (%) With Events	68 (62.4%)	69 (62.2%)	
Patients (%) Without Events (Censored)	41 (37.6%)	42 (37.8%)	
Median PFS (months) [b]	4.2	4.0	
95% CI	(2.9, 6.7)	(2.7, 4.4)	
Hazard Ratio (Relative to TPC) [c]			0.727
95% CI for Hazard Ratio			(0.515, 1.024)
p-value			0.0678

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.9859
Stratification factor of visceral metastasis: Yes			
Total Patients	196	205	
Patients (%) With Events	129 (65.8%)	136 (66.3%)	
Patients (%) Without Events (Censored)	67 (34.2%)	69 (33.7%)	
Median PFS (months) [b]	4.7	4.0	
95% CI	(4.1, 6.0)	(3.0, 4.4)	
Hazard Ratio (Relative to TPC) [c]			0.675
95% CI for Hazard Ratio			(0.527, 0.862)
p-value			0.0016
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	6 (66.7%)	6 (75.0%)	
Patients (%) Without Events (Censored)	3 (33.3%)	2 (25.0%)	
Median PFS (months) [b]	6.7	1.6	
95% CI	(0.5, NE)	(0.9, NE)	
Hazard Ratio (Relative to TPC) [c]			0.690
95% CI for Hazard Ratio			(0.207, 2.302)
p-value			0.5554

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.1380
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	183	185	
Patients (%) With Events	119 (65.0%)	125 (67.6%)	
Patients (%) Without Events (Censored)	64 (35.0%)	60 (32.4%)	
Median PFS (months) [b]	5.3	4.1	
95% CI	(4.1, 7.2)	(3.0, 4.4)	
Hazard Ratio (Relative to TPC) [c]			0.635
95% CI for Hazard Ratio			(0.491, 0.821)
p-value			0.0005
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	22	28	
Patients (%) With Events	16 (72.7%)	17 (60.7%)	
Patients (%) Without Events (Censored)	6 (27.3%)	11 (39.3%)	
Median PFS (months) [b]	2.9	2.8	
95% CI	(1.5, 5.8)	(1.4, 6.1)	
Hazard Ratio (Relative to TPC) [c]			1.113
95% CI for Hazard Ratio			(0.561, 2.208)
p-value			0.7489

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.8282
Age group: < 65 years			
Total Patients	158	161	
Patients (%) With Events	107 (67.7%)	109 (67.7%)	
Patients (%) Without Events (Censored)	51 (32.3%)	52 (32.3%)	
Median PFS (months) [b]	4.6	4.0	
95% CI	(3.3, 6.4)	(2.8, 4.3)	
Hazard Ratio (Relative to TPC) [c]			0.668
95% CI for Hazard Ratio			(0.509, 0.878)
p-value			0.0035
Age group: >= 65 years			
Total Patients	47	52	
Patients (%) With Events	28 (59.6%)	33 (63.5%)	
Patients (%) Without Events (Censored)	19 (40.4%)	19 (36.5%)	
Median PFS (months) [b]	5.5	4.4	
95% CI	(3.7, 8.5)	(2.1, 5.6)	
Hazard Ratio (Relative to TPC) [c]			0.675
95% CI for Hazard Ratio			(0.402, 1.132)
p-value			0.1364

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.2920
Race: White			
Total Patients	143	143	
Patients (%) With Events	99 (69.2%)	95 (66.4%)	
Patients (%) Without Events (Censored)	44 (30.8%)	48 (33.6%)	
Median PFS (months) [b]	4.7	4.1	
95% CI	(4.1, 6.7)	(3.0, 4.5)	
Hazard Ratio (Relative to TPC) [c]			0.660
95% CI for Hazard Ratio			(0.494, 0.880)
p-value			0.0045
Race: Non-white			
Total Patients	14	18	
Patients (%) With Events	10 (71.4%)	13 (72.2%)	
Patients (%) Without Events (Censored)	4 (28.6%)	5 (27.8%)	
Median PFS (months) [b]	2.6	1.9	
95% CI	(1.4, NE)	(1.4, 8.9)	
Hazard Ratio (Relative to TPC) [c]			1.266
95% CI for Hazard Ratio			(0.535, 2.997)
p-value			0.6377

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.1633
Screening ECOG Status: 0			
Total Patients	90	99	
Patients (%) With Events	55 (61.1%)	64 (64.6%)	
Patients (%) Without Events (Censored)	35 (38.9%)	35 (35.4%)	
Median PFS (months) [b]	5.7	4.0	
95% CI	(4.1, 8.4)	(1.9, 5.6)	
Hazard Ratio (Relative to TPC) [c]			0.573
95% CI for Hazard Ratio			(0.395, 0.830)
p-value			0.0030
Screening ECOG Status: 1			
Total Patients	115	114	
Patients (%) With Events	80 (69.6%)	78 (68.4%)	
Patients (%) Without Events (Censored)	35 (30.4%)	36 (31.6%)	
Median PFS (months) [b]	4.2	4.0	
95% CI	(3.1, 5.8)	(2.8, 4.5)	
Hazard Ratio (Relative to TPC) [c]			0.774
95% CI for Hazard Ratio			(0.564, 1.063)
p-value			0.1150

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.6332
Geographic Region: Europe			
Total Patients	125	130	
Patients (%) With Events	79 (63.2%)	93 (71.5%)	
Patients (%) Without Events (Censored)	46 (36.8%)	37 (28.5%)	
Median PFS (months) [b]	5.3	4.1	
95% CI	(3.3, 7.4)	(2.8, 4.5)	
Hazard Ratio (Relative to TPC) [c]			0.644
95% CI for Hazard Ratio			(0.473, 0.876)
p-value			0.0048
Geographic Region: North America			
Total Patients	80	83	
Patients (%) With Events	56 (70.0%)	49 (59.0%)	
Patients (%) Without Events (Censored)	24 (30.0%)	34 (41.0%)	
Median PFS (months) [b]	4.7	3.7	
95% CI	(3.7, 7.0)	(1.9, 4.4)	
Hazard Ratio (Relative to TPC) [c]			0.741
95% CI for Hazard Ratio			(0.503, 1.092)
p-value			0.1270

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.3200
Prior CDK treatment duration: <= 12 months			
Total Patients	118	128	
Patients (%) With Events	75 (63.6%)	90 (70.3%)	
Patients (%) Without Events (Censored)	43 (36.4%)	38 (29.7%)	
Median PFS (months) [b]	5.6	3.7	
95% CI	(4.2, 7.2)	(2.8, 4.3)	
Hazard Ratio (Relative to TPC) [c]			0.589
95% CI for Hazard Ratio			(0.430, 0.807)
p-value			0.0009
Prior CDK treatment duration: > 12 months			
Total Patients	82	82	
Patients (%) With Events	56 (68.3%)	50 (61.0%)	
Patients (%) Without Events (Censored)	26 (31.7%)	32 (39.0%)	
Median PFS (months) [b]	4.1	4.2	
95% CI	(3.1, 7.0)	(2.7, 5.6)	
Hazard Ratio (Relative to TPC) [c]			0.789
95% CI for Hazard Ratio			(0.535, 1.163)
p-value			0.2307

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.0018
Early relapse: Yes			
Total Patients	13	17	
Patients (%) With Events	8 (61.5%)	13 (76.5%)	
Patients (%) Without Events (Censored)	5 (38.5%)	4 (23.5%)	
Median PFS (months) [b]	5.7	1.4	
95% CI	(2.7, NE)	(1.1, 1.6)	
Hazard Ratio (Relative to TPC) [c]			0.101
95% CI for Hazard Ratio			(0.030, 0.336)
p-value			<0.0001
Early relapse: No			
Total Patients	185	192	
Patients (%) With Events	124 (67.0%)	126 (65.6%)	
Patients (%) Without Events (Censored)	61 (33.0%)	66 (34.4%)	
Median PFS (months) [b]	4.6	4.2	
95% CI	(3.7, 6.4)	(3.1, 4.5)	
Hazard Ratio (Relative to TPC) [c]			0.741
95% CI for Hazard Ratio			(0.575, 0.954)
p-value			0.0197

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.3993
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	181	187	
Patients (%) With Events	122 (67.4%)	125 (66.8%)	
Patients (%) Without Events (Censored)	59 (32.6%)	62 (33.2%)	
Median PFS (months) [b]	4.2	4.0	
95% CI	(3.3, 5.6)	(3.0, 4.4)	
Hazard Ratio (Relative to TPC) [c]			0.703
95% CI for Hazard Ratio			(0.545, 0.908)
p-value			0.0068
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	26	
Patients (%) With Events	13 (54.2%)	17 (65.4%)	
Patients (%) Without Events (Censored)	11 (45.8%)	9 (34.6%)	
Median PFS (months) [b]	8.5	2.8	
95% CI	(4.4, 12.7)	(1.4, 7.1)	
Hazard Ratio (Relative to TPC) [c]			0.510
95% CI for Hazard Ratio			(0.246, 1.055)
p-value			0.0663

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.0735
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	125	145	
Patients (%) With Events	79 (63.2%)	99 (68.3%)	
Patients (%) Without Events (Censored)	46 (36.8%)	46 (31.7%)	
Median PFS (months) [b]	5.5	3.1	
95% CI	(4.1, 7.1)	(2.3, 4.1)	
Hazard Ratio (Relative to TPC) [c]			0.586
95% CI for Hazard Ratio			(0.433, 0.792)
p-value			0.0005
Chemotherapy in neo/adjuvant setting: No			
Total Patients	80	68	
Patients (%) With Events	56 (70.0%)	43 (63.2%)	
Patients (%) Without Events (Censored)	24 (30.0%)	25 (36.8%)	
Median PFS (months) [b]	4.1	4.5	
95% CI	(2.8, 7.0)	(4.0, 7.1)	
Hazard Ratio (Relative to TPC) [c]			0.904
95% CI for Hazard Ratio			(0.604, 1.354)
p-value			0.6299

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.7691
Trop2: H-Score < 100			
Total Patients	68	73	
Patients (%) With Events	45 (66.2%)	49 (67.1%)	
Patients (%) Without Events (Censored)	23 (33.8%)	24 (32.9%)	
Median PFS (months) [b]	4.2	4.0	
95% CI	(2.9, 6.0)	(2.7, 5.6)	
Hazard Ratio (Relative to TPC) [c]			0.876
95% CI for Hazard Ratio			(0.585, 1.314)
p-value			0.5221
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	78	
Patients (%) With Events	47 (66.2%)	54 (69.2%)	
Patients (%) Without Events (Censored)	24 (33.8%)	24 (30.8%)	
Median PFS (months) [b]	4.7	2.3	
95% CI	(3.2, 7.4)	(1.5, 4.2)	
Hazard Ratio (Relative to TPC) [c]			0.512
95% CI for Hazard Ratio			(0.340, 0.771)
p-value			0.0011

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Trop2: H-Score > 200			
Total Patients	42	26	
Patients (%) With Events	29 (69.0%)	21 (80.8%)	
Patients (%) Without Events (Censored)	13 (31.0%)	5 (19.2%)	
Median PFS (months) [b]	4.6	5.6	
95% CI	(1.5, 11.2)	(4.1, 5.7)	
Hazard Ratio (Relative to TPC) [c]			0.780
95% CI for Hazard Ratio			(0.436, 1.394)
p-value			0.4047

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Interaction p-value [a]			0.0020
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	15 (71.4%)	15 (65.2%)	
Patients (%) Without Events (Censored)	6 (28.6%)	8 (34.8%)	
Median PFS (months) [b]	4.4	4.5	
95% CI	(1.5, 7.1)	(1.6, 6.4)	
Hazard Ratio (Relative to TPC) [c]			1.183
95% CI for Hazard Ratio			(0.569, 2.459)
p-value			0.6522
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	128	130	
Patients (%) With Events	81 (63.3%)	89 (68.5%)	
Patients (%) Without Events (Censored)	47 (36.7%)	41 (31.5%)	
Median PFS (months) [b]	5.5	4.4	
95% CI	(4.0, 7.1)	(4.0, 5.6)	
Hazard Ratio (Relative to TPC) [c]			0.729
95% CI for Hazard Ratio			(0.536, 0.990)
p-value			0.0432

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.2.1.6: Progression Free Survival (PFS) per BICR by Selected Subgroup for Interim Analysis 2 Data
ITT Population
Excluding Participants Pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	56	60	
Patients (%) With Events	39 (69.6%)	38 (63.3%)	
Patients (%) Without Events (Censored)	17 (30.4%)	22 (36.7%)	
Median PFS (months) [b]	4.2	1.6	
95% CI	(3.1, 8.4)	(1.4, 2.6)	
Hazard Ratio (Relative to TPC) [c]			0.368
95% CI for Hazard Ratio			(0.225, 0.602)
p-value			<0.0001

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
PFS is defined as the number of months (30.4375 days) from the date of randomization to the date of the first radiological disease progression per RECIST 1.1 or death due to any cause, whichever comes first. Interim Analysis 2 has data cut at 7/1/2022.
[a] Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
[b] Median PFS is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE = Not Estimable.
[c] Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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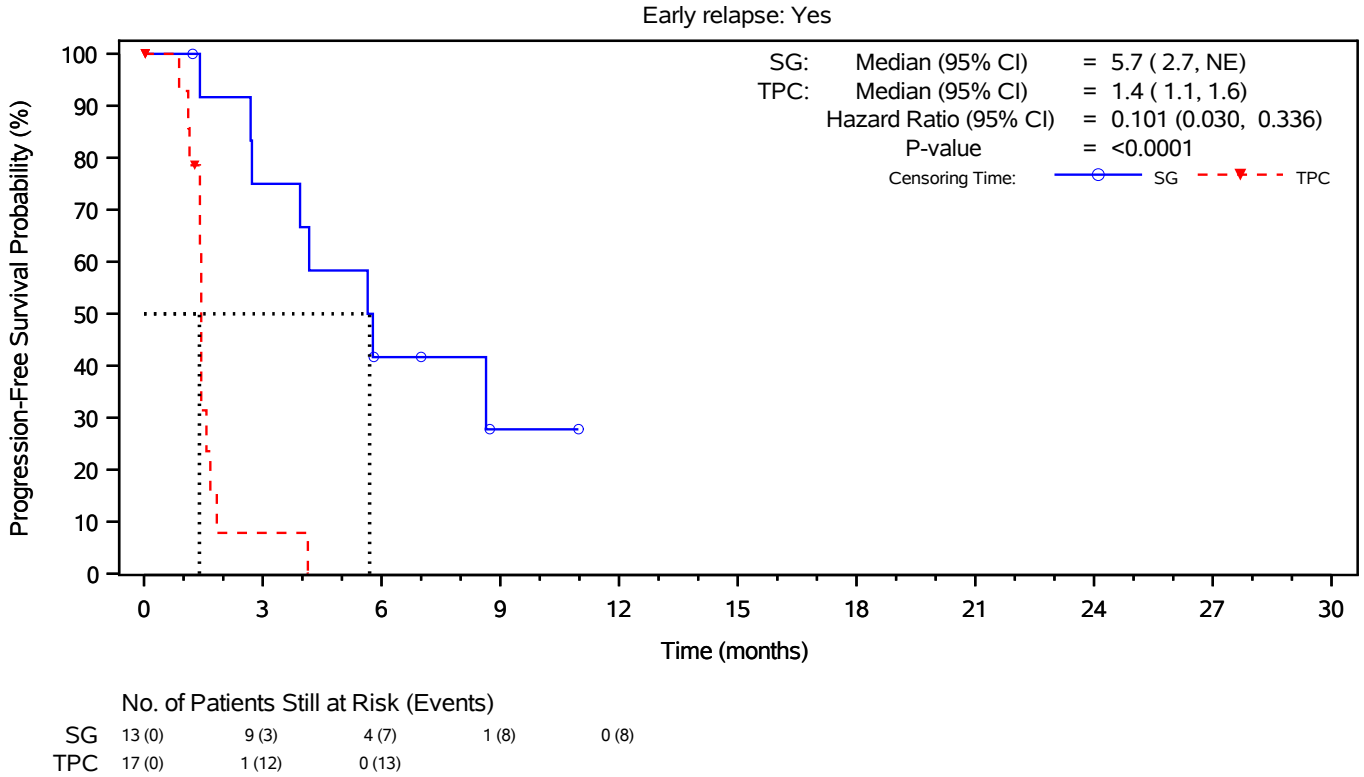
Figure 15.2.1.4.9: Kaplan-Meier Estimates of PFS per BICR for Interim Analysis 2 Data by Early Relapse
ITT Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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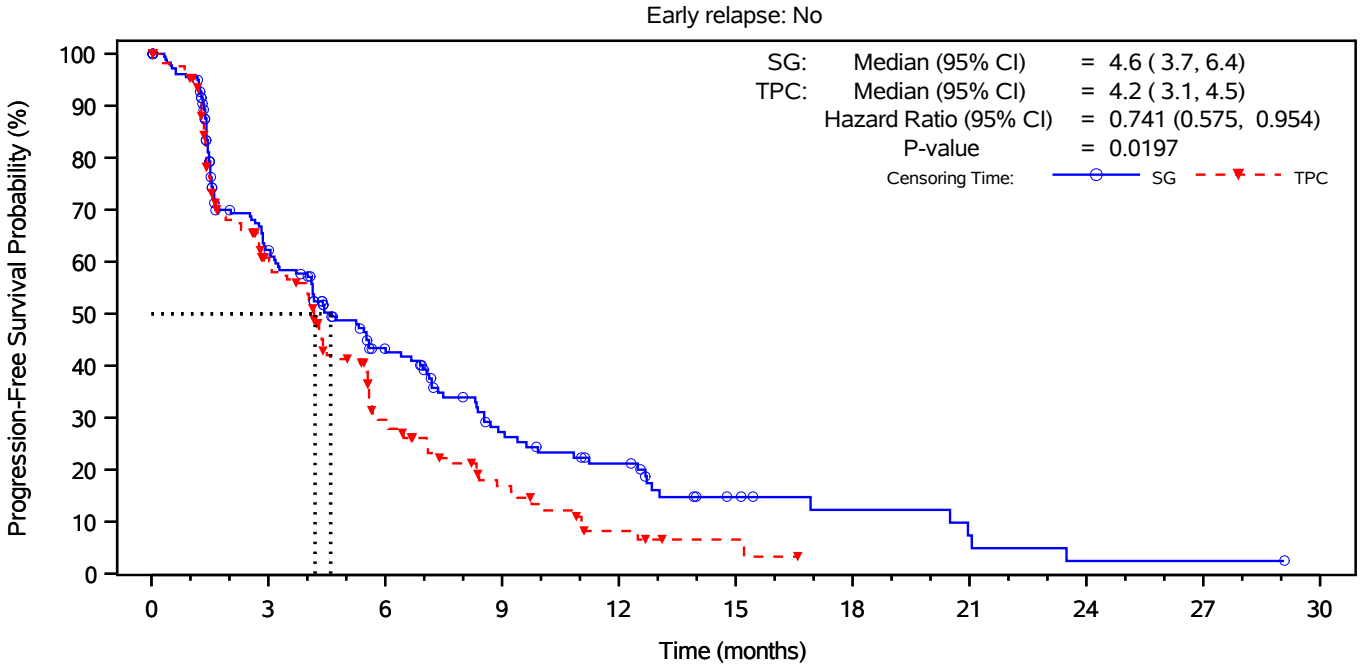
Figure 15.2.1.4.9: Kaplan-Meier Estimates of PFS per BICR for Interim Analysis 2 Data by Early Relapse
ITT Population
Excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	185 (0)	97 (63)	53 (90)	28 (108)	19 (114)	8 (119)	5 (120)	3 (122)	1 (124)	1 (124)	0 (124)
TPC	192 (0)	87 (63)	34 (104)	15 (117)	5 (124)	2 (125)	0 (126)				

The analysis is based on Interim 2 data cut at 01Jul2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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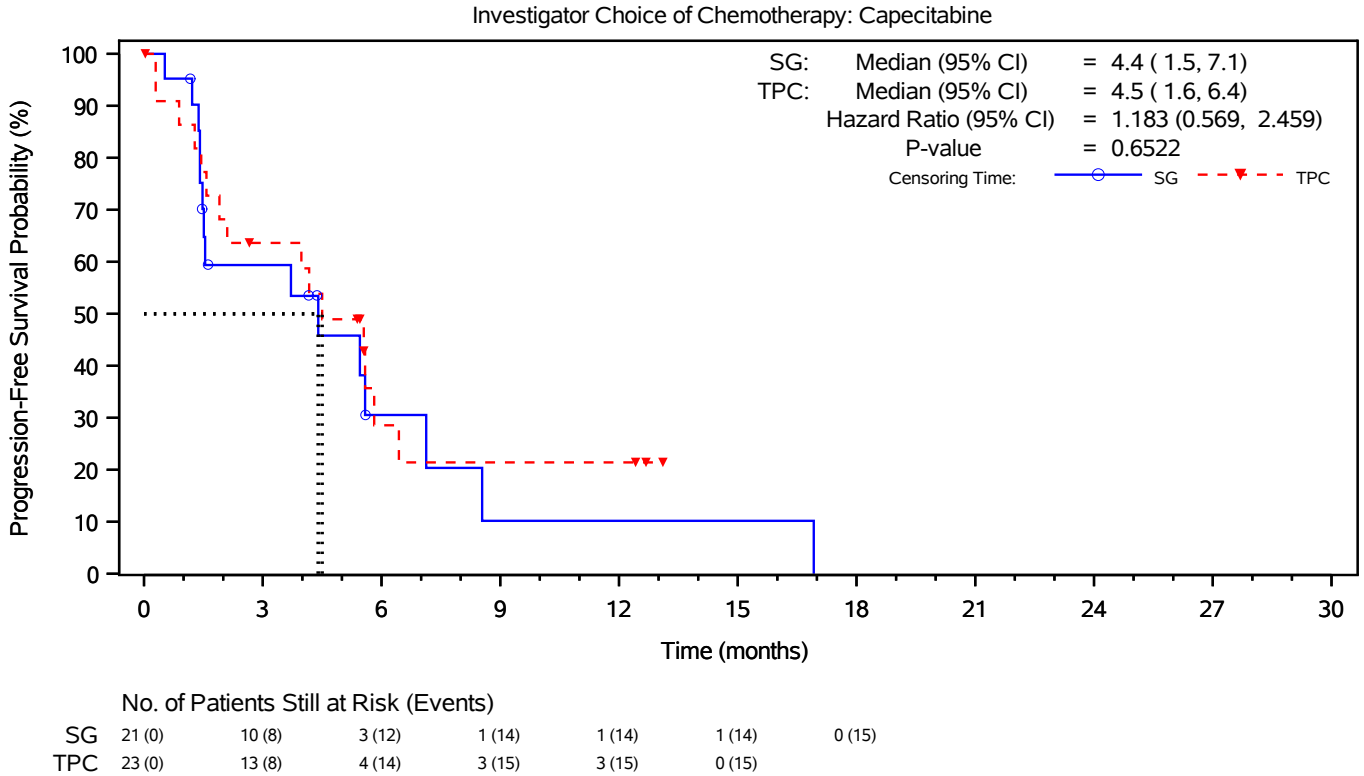
Figure 15.2.1.4.13: Kaplan-Meier Estimates of PFS per BICR for Interim Analysis 2 Data by Investigator Choice of Chemotherapy Prior to Randomization
ITT Population
Excluding participants pre-selected to Gemcitabine



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Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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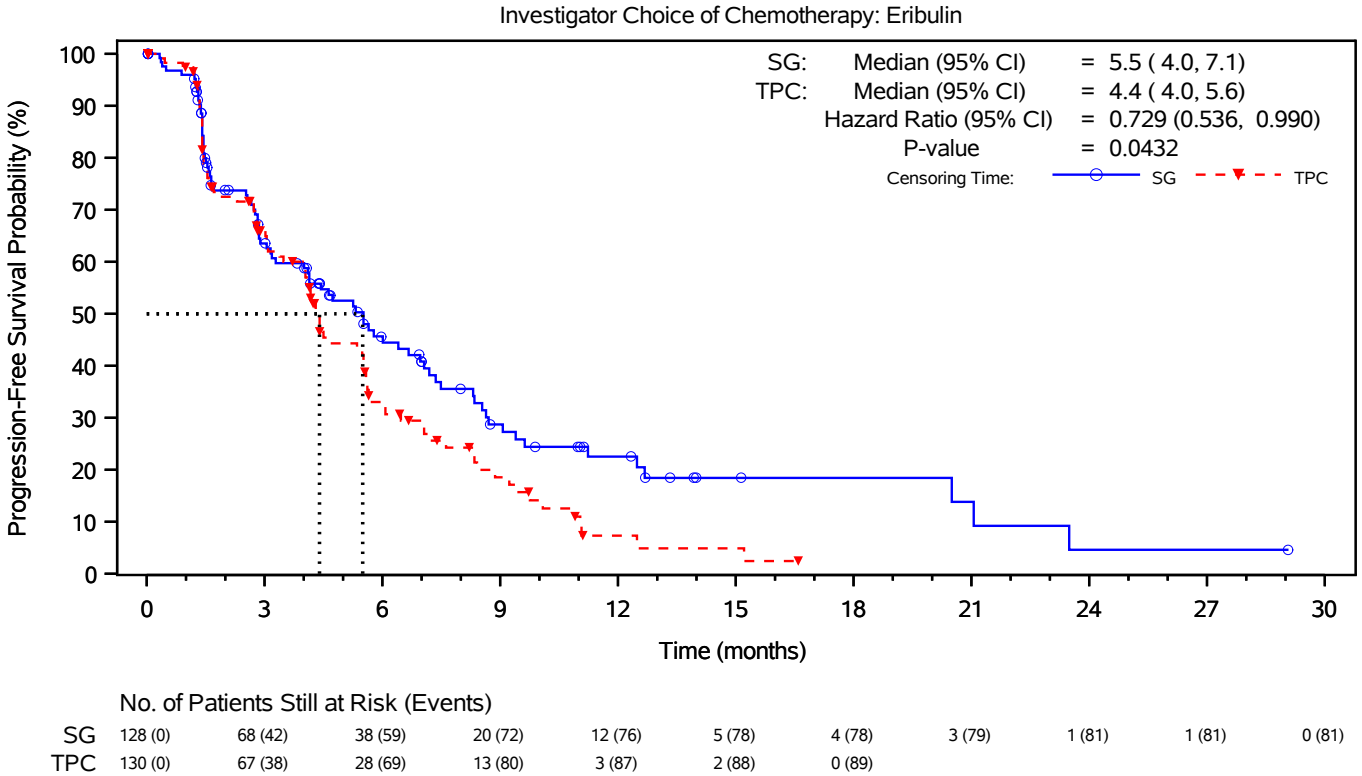
Figure 15.2.1.4.13: Kaplan-Meier Estimates of PFS per BICR for Interim Analysis 2 Data by Investigator Choice of Chemotherapy Prior to Randomization
ITT Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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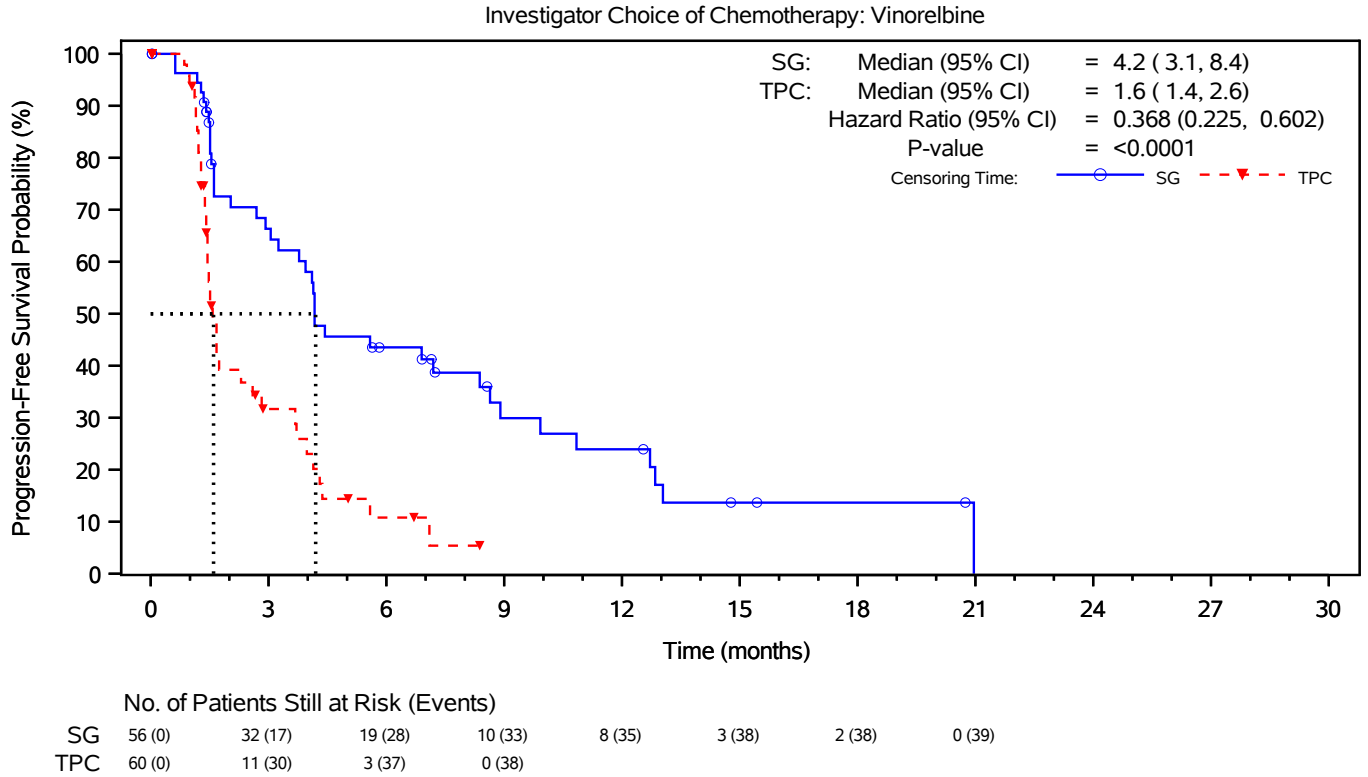
Figure 15.2.1.4.13: Kaplan-Meier Estimates of PFS per BICR for Interim Analysis 2 Data by Investigator Choice of Chemotherapy Prior to Randomization
ITT Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Anhang 4-G 5: Tumoransprechen

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Table 15.2.3.1: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) and Best Overall Response (BOR) per BICR
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Patients with Measurable Disease at Baseline	203	210	
Objective Response (CR or PR)			
n (%)	43 (21.0%)	32 (15.0%)	
95% CI (Exact)	(15.6, 27.2)	(10.5, 20.5)	
Odds Ratio			1.501
95% CI			(0.909, 2.479)
P-value			0.1101
Relative Risk (RR)			1.399
95% CI (Exact)			(0.924, 2.120)
P-value			0.1101
Risk Difference (RD)			0.060
95% CI (Wald)			(-0.014, 0.134)
P-value			0.1111

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR and PR is confirmed no less than 4 weeks later. SD requires a minimum duration of 6 weeks to be classified as SD.
Clinical benefit rate (CBR) is defined as the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
CIs for odds ratio and RR are from stratified Cochran-Mantel-Haenszel method, CIs for RD are derived from Wald method.

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Table 15.2.3.1: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) and Best Overall Response (BOR) per BICR
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Clinical Benefit Rate (CR, PR or SD >= 6 months)			
n (%)	69 (33.7%)	51 (23.9%)	
95% CI (Exact)	(27.2, 40.6)	(18.4, 30.3)	
Odds Ratio			1.600
95% CI			(1.045, 2.450)
P-value			0.0309
Relative Risk (RR)			1.402
95% CI (Exact)			(1.030, 1.908)
P-value			0.0309
Risk Difference (RD)			0.096
95% CI (Wald)			(0.010, 0.183)
P-value			0.0296
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.0%)	0	
Partial Response (PR)	41 (20.0%)	32 (15.0%)	
Stable Disease (SD)	101 (49.3%)	83 (39.0%)	
SD >= 6 months	26 (12.7%)	19 (8.9%)	
Progressive Disease (PD)	48 (23.4%)	58 (27.2%)	
Not Evaluable	13 (6.3%)	40 (18.8%)	

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR and PR is confirmed no less than 4 weeks later. SD requires a minimum duration of 6 weeks to be classified as SD.
Clinical benefit rate (CBR) is defined as the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
CIs for odds ratio and RR are from stratified Cochran-Mantel-Haenszel method, CIs for RD are derived from Wald method.

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Table 15.2.3.3: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) and Best Overall Response (BOR) per LIR
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Patients with Measurable Disease at Baseline	205	212	
Objective Response (CR or PR)			
n (%)	37 (18.0%)	21 (9.9%)	
95% CI (Exact)	(13.0, 24.0)	(6.2, 14.7)	
Odds Ratio			2.021
95% CI			(1.137, 3.591)
P-value			0.0150
Relative Risk (RR)			1.829
95% CI (Exact)			(1.111, 3.011)
P-value			0.0150
Risk Difference (RD)			0.082
95% CI (Wald)			(0.016, 0.148)
P-value			0.0151

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
The best overall response is derived based on the tumor response per LIR at each tumor assessment according to RECIST 1.1. Response of CR and PR is confirmed no less than 4 weeks later. SD requires a minimum duration of 6 weeks to be classified as SD.
Clinical benefit rate (CBR) is defined as the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
CIs for odds ratio and RR are from stratified Cochran-Mantel-Haenszel method, CIs for RD are derived from Wald method.

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Table 15.2.3.3: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) and Best Overall Response (BOR) per LIR
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N = 205)	TPC (N = 213)	Treatment Comparison
Clinical Benefit Rate (CR, PR or SD >= 6 months)			
n (%)	67 (32.7%)	49 (23.0%)	
95% CI (Exact)	(26.3, 39.6)	(17.5, 29.2)	
Odds Ratio			1.637
95% CI			(1.058, 2.534)
P-value			0.0272
Relative Risk (RR)			1.419
95% CI (Exact)			(1.039, 1.938)
P-value			0.0272
Risk Difference (RD)			0.096
95% CI (Wald)			(0.012, 0.181)
P-value			0.0258
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	37 (18.0%)	21 (9.9%)	
Stable Disease (SD)	96 (46.8%)	89 (41.8%)	
SD >= 6 months	30 (14.6%)	28 (13.1%)	
Progressive Disease (PD)	57 (27.8%)	63 (29.6%)	
Not Evaluable	15 (7.3%)	40 (18.8%)	

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
The best overall response is derived based on the tumor response per LIR at each tumor assessment according to RECIST 1.1. Response of CR and PR is confirmed no less than 4 weeks later. SD requires a minimum duration of 6 weeks to be classified as SD.
Clinical benefit rate (CBR) is defined as the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
CIs for odds ratio and RR are from stratified Cochran-Mantel-Haenszel method, CIs for RD are derived from Wald method.

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Table 15.2.4.1: Duration of Response (DOR) for Objective Responders per Blinded Independent Central Review (BICR)
ITT Population
Only including participants with Confirmed Objective Response but excluding participants pre-selected to Gemcitabine

	SG (N = 43)	TPC (N = 32)	Treatment Comparison
Number of Responders (CR or PR)	43	32	
Subjects With Events [n(%)]	25 (58.1%)	20 (62.5%)	
Subjects Without Events (Censored) [n(%)]	18 (41.9%)	12 (37.5%)	
Median Duration of Response (months) [a]	7.4	5.1	
95% CI	(5.8, 8.9)	(2.9, 7.5)	
Log-rank P-value (Stratified) [b]			0.0212
Stratified Cox Regression analysis [b]			
Hazard Ratio (Relative to TPC)			0.485
95% CI for Hazard Ratio			(0.260, 0.906)
Kaplan-Meier Estimates of DOR Rate (%) (95% CI) [c]			
At 3 Months	92.7 (79.0, 97.6)	67.0 (45.9, 81.3)	
At 6 Months	65.7 (48.1, 78.5)	39.1 (19.8, 58.1)	
At 9 Months	30.9 (14.9, 48.6)	11.4 (2.0, 29.8)	
At 12 Months	22.1 (8.5, 39.6)	NE (NE, NE)	

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
Only patients achieving confirmed CR or PR are included in the analysis. DOR is defined as the number of months (30.4375 days) from the date of initial response to the date of the event defined as the first documented progression per RECIST 1.1 or death due to any cause, whichever is earlier.
[a] Median DOR is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE=Not Estimable.
[b] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).

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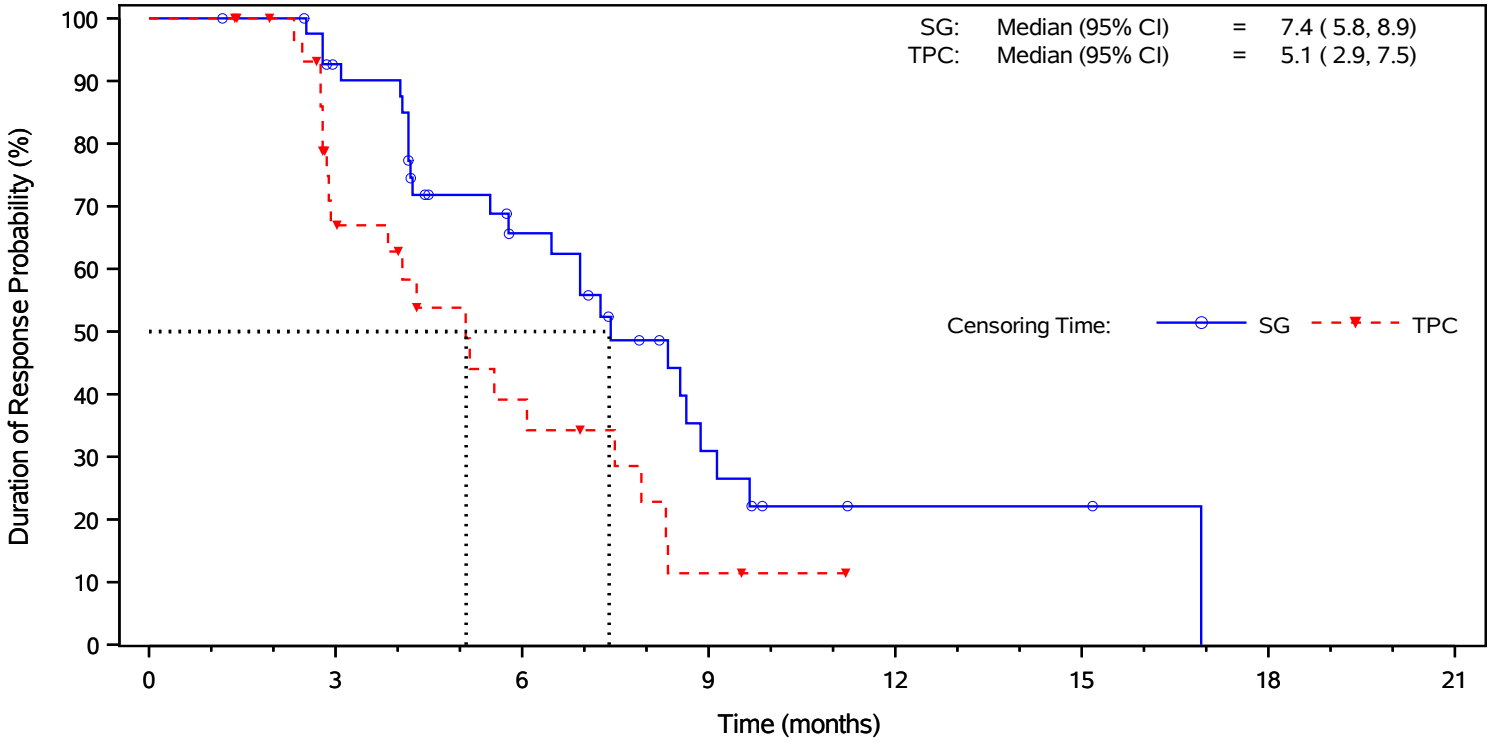
Figure 15.2.3.1: Kaplan-Meier Estimates of Duration of Response (DOR) per Blinded Independent Central Review (BICR)
ITT Population
Only including participants with Confirmed Objective Response but excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	43 (0)	36 (3)	20 (13)	7 (22)	2 (24)	2 (24)	0 (25)
TPC	32 (0)	17 (9)	8 (15)	2 (20)	0 (20)		

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Table 15.2.4.2: Duration of Response (DOR) for Objective Responders per Local Investigator Review (LIR)
ITT Population
Only including participants with Confirmed Objective Response but excluding participants pre-selected to Gemcitabine

	SG (N = 37)	TPC (N = 21)	Treatment Comparison
Number of Responders (CR or PR)	37	21	
Subjects With Events [n(%)]	31 (83.8%)	17 (81.0%)	
Subjects Without Events (Censored) [n(%)]	6 (16.2%)	4 (19.0%)	
Median Duration of Response (months) [a]	7.4	4.3	
95% CI	(5.4, 9.2)	(4.2, 6.1)	
Log-rank P-value (Stratified) [b]			0.0139
Stratified Cox Regression analysis [b]			
Hazard Ratio (Relative to TPC)			0.418
95% CI for Hazard Ratio			(0.206, 0.849)
Kaplan-Meier Estimates of DOR Rate (%) (95% CI) [c]			
At 3 Months	94.4 (79.3, 98.6)	85.0 (60.4, 94.9)	
At 6 Months	56.3 (38.2, 70.9)	37.3 (15.7, 59.1)	
At 9 Months	34.6 (19.2, 50.6)	18.6 (4.6, 39.9)	
At 12 Months	12.0 (3.2, 26.9)	NE (NE, NE)	

The denominator is the number of patients in the ITT Population excluding participants assigned to Gemcitabine before randomized for each treatment group.
Only patients achieving confirmed CR or PR are included in the analysis. DOR is defined as the number of months (30.4375 days) from the date of initial response to the date of the event defined as the first documented progression per RECIST 1.1 or death due to any cause, whichever is earlier.
[a] Median DOR is from Kaplan-Meier estimate. CI for median is computed using the Brookmeyer-Crowley method. NE=Not Estimable.
[b] Stratified log-rank test and stratified Cox regression adjusted for stratification factors (IXRS): prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Y/N), and endocrine therapy in the metastatic setting for at least 6 months (Y/N).

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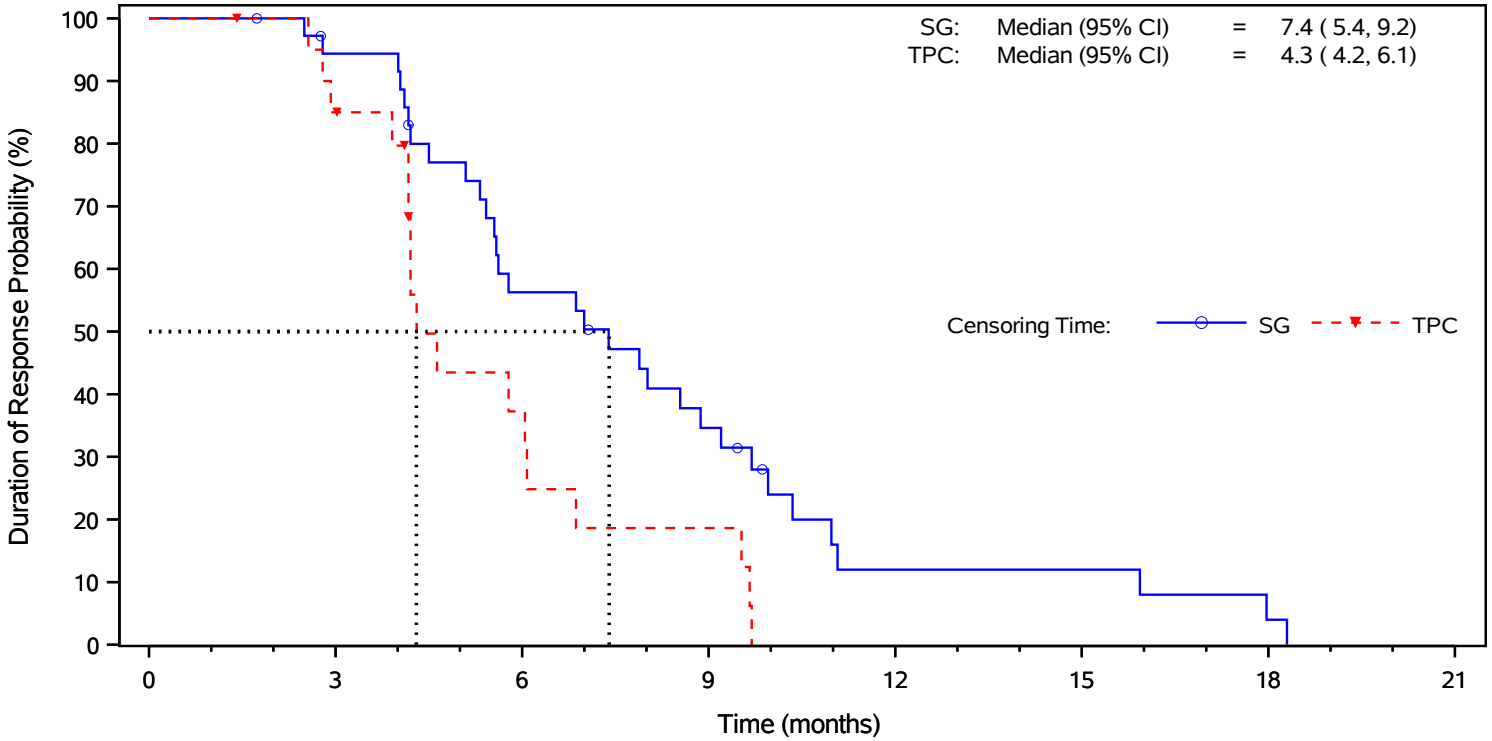
Figure 15.2.3.2: Kaplan-Meier Estimates of Duration of Response (DOR) per Local Investigator Review (LIR)
ITT Population
Only including participants with Confirmed Objective Response but excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	37 (0)	33 (2)	19 (15)	11 (22)	3 (28)	3 (28)	1 (30)	0 (31)
TPC	21 (0)	17 (3)	6 (11)	3 (14)	0 (17)			

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Anhang 4-G 5.1: Subgruppenanalysen

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Stratification factor of prior chemotherapy regimens for treatment of metastatic disease			
ORR Relative Risk Cochran's Q p-value			0.0205
CBR Relative Risk Cochran's Q p-value			0.3307
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2	96	102	
Objective Response (CR or PR)			
n (%)	29 (30.2%)	14 (13.7%)	
95% CI (Exact)	(21.3, 40.4)	(7.7, 22.0)	
Odds Ratio			2.721
95% CI (Exact)			(1.334, 5.548)
P-value			0.0050
Relative Risk			2.201
95% CI (Exact)			(1.240, 3.906)
P-value			0.0050
Risk Difference			0.165
95% CI (Wald)			(0.051, 0.278)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2	96	102	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	37 (38.5%)	24 (23.5%)	
95% CI (Exact)	(28.8, 49.0)	(15.7, 33.0)	
Odds Ratio			2.038
95% CI (Exact)			(1.102, 3.770)
P-value			0.0226
Relative Risk			1.638
95% CI (Exact)			(1.064, 2.522)
P-value			0.0226
Risk Difference			0.150
95% CI (Wald)			(0.023, 0.278)
Best Overall Response, n (%)			
Complete Response (CR)	1 (1.0%)	0	
Partial Response (PR)	28 (29.2%)	14 (13.7%)	
Stable Disease (SD)	39 (40.6%)	40 (39.2%)	
SD >= 6 months	8 (8.3%)	10 (9.8%)	
Progressive Disease (PD)	23 (24.0%)	29 (28.4%)	
Not Evaluable	5 (5.2%)	19 (18.6%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4	109	111	
Objective Response (CR or PR)			
n (%)	14 (12.8%)	18 (16.2%)	
95% CI (Exact)	(7.2, 20.6)	(9.9, 24.4)	
Odds Ratio			0.761
95% CI (Exact)			(0.358, 1.619)
P-value			0.4791
Relative Risk			0.792
95% CI (Exact)			(0.415, 1.512)
P-value			0.4791
Risk Difference			-0.034
95% CI (Wald)			(-0.127, 0.059)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4	109	111	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	32 (29.4%)	27 (24.3%)	
95% CI (Exact)	(21.0, 38.8)	(16.7, 33.4)	
Odds Ratio			1.293
95% CI (Exact)			(0.711, 2.352)
P-value			0.4005
Relative Risk			1.207
95% CI (Exact)			(0.778, 1.872)
P-value			0.4005
Risk Difference			0.050
95% CI (Wald)			(-0.067, 0.167)
Best Overall Response, n (%)			
Complete Response (CR)	1 (0.9%)	0	
Partial Response (PR)	13 (11.9%)	18 (16.2%)	
Stable Disease (SD)	62 (56.9%)	43 (38.7%)	
SD >= 6 months	18 (16.5%)	9 (8.1%)	
Progressive Disease (PD)	25 (22.9%)	29 (26.1%)	
Not Evaluable	8 (7.3%)	21 (18.9%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Stratification factor of visceral metastasis			
ORR Relative Risk Cochran's Q p-value			0.8265
CBR Relative Risk Cochran's Q p-value			0.7358
Stratification factor of visceral metastasis: Yes	196	205	
Objective Response (CR or PR)			
n (%)	41 (20.9%)	31 (15.1%)	
95% CI (Exact)	(15.4, 27.3)	(10.5, 20.8)	
Odds Ratio			1.485
95% CI (Exact)			(0.888, 2.483)
P-value			0.1311
Relative Risk			1.383
95% CI (Exact)			(0.906, 2.113)
P-value			0.1311
Risk Difference			0.058
95% CI (Wald)			(-0.017, 0.133)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of visceral metastasis: Yes	196	205	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	65 (33.2%)	49 (23.9%)	
95% CI (Exact)	(26.6, 40.2)	(18.2, 30.3)	
Odds Ratio			1.580
95% CI (Exact)			(1.020, 2.447)
P-value			0.0401
Relative Risk			1.387
95% CI (Exact)			(1.013, 1.901)
P-value			0.0401
Risk Difference			0.093
95% CI (Wald)			(0.005, 0.181)
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.0%)	0	
Partial Response (PR)	39 (19.9%)	31 (15.1%)	
Stable Disease (SD)	98 (50.0%)	81 (39.5%)	
SD >= 6 months	24 (12.2%)	18 (8.8%)	
Progressive Disease (PD)	44 (22.4%)	53 (25.9%)	
Not Evaluable	13 (6.6%)	40 (19.5%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of visceral metastasis: No	9	8	
Objective Response (CR or PR)			
n (%)	2 (22.2%)	1 (12.5%)	
95% CI (Exact)	(2.8, 60.0)	(0.3, 52.7)	
Odds Ratio			2.000
95% CI (Exact)			(0.146, 27.447)
P-value			0.6106
Relative Risk			1.778
95% CI (Exact)			(0.196, 16.100)
P-value			0.6106
Risk Difference			0.097
95% CI (Wald)			(-0.258, 0.453)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of visceral metastasis: No	9	8	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	4 (44.4%)	2 (25.0%)	
95% CI (Exact)	(13.7, 78.8)	(3.2, 65.1)	
Odds Ratio			2.400
95% CI (Exact)			(0.303, 19.041)
P-value			0.4166
Relative Risk			1.778
95% CI (Exact)			(0.436, 7.246)
P-value			0.4166
Risk Difference			0.194
95% CI (Wald)			(-0.248, 0.637)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	2 (22.2%)	1 (12.5%)	
Stable Disease (SD)	3 (33.3%)	2 (25.0%)	
SD >= 6 months	2 (22.2%)	1 (12.5%)	
Progressive Disease (PD)	4 (44.4%)	5 (62.5%)	
Not Evaluable	0	0	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Stratification factor of endocrine therapy in the metastatic setting for >=6 months			
ORR Relative Risk Cochran's Q p-value			0.5064
CBR Relative Risk Cochran's Q p-value			0.8994
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes	183	185	
Objective Response (CR or PR)			
n (%)	38 (20.8%)	29 (15.7%)	
95% CI (Exact)	(15.1, 27.4)	(10.8, 21.7)	
Odds Ratio			1.410
95% CI (Exact)			(0.827, 2.404)
P-value			0.2065
Relative Risk			1.325
95% CI (Exact)			(0.855, 2.053)
P-value			0.2065
Risk Difference			0.051
95% CI (Wald)			(-0.028, 0.130)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes	183	185	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	62 (33.9%)	45 (24.3%)	
95% CI (Exact)	(27.1, 41.2)	(18.3, 31.2)	
Odds Ratio			1.594
95% CI (Exact)			(1.012, 2.511)
P-value			0.0439
Relative Risk			1.393
95% CI (Exact)			(1.006, 1.928)
P-value			0.0439
Risk Difference			0.096
95% CI (Wald)			(0.003, 0.188)
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.1%)	0	
Partial Response (PR)	36 (19.7%)	29 (15.7%)	
Stable Disease (SD)	93 (50.8%)	74 (40.0%)	
SD >= 6 months	24 (13.1%)	16 (8.6%)	
Progressive Disease (PD)	44 (24.0%)	51 (27.6%)	
Not Evaluable	8 (4.4%)	31 (16.8%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No	22	28	
Objective Response (CR or PR)			
n (%)	5 (22.7%)	3 (10.7%)	
95% CI (Exact)	(7.8, 45.4)	(2.3, 28.2)	
Odds Ratio			2.451
95% CI (Exact)			(0.516, 11.644)
P-value			0.2549
Relative Risk			2.121
95% CI (Exact)			(0.568, 7.924)
P-value			0.2549
Risk Difference			0.120
95% CI (Wald)			(-0.089, 0.329)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No	22	28	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	7 (31.8%)	6 (21.4%)	
95% CI (Exact)	(13.9, 54.9)	(8.3, 41.0)	
Odds Ratio			1.711
95% CI (Exact)			(0.479, 6.109)
P-value			0.4105
Relative Risk			1.485
95% CI (Exact)			(0.582, 3.788)
P-value			0.4105
Risk Difference			0.104
95% CI (Wald)			(-0.143, 0.351)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	5 (22.7%)	3 (10.7%)	
Stable Disease (SD)	8 (36.4%)	9 (32.1%)	
SD >= 6 months	2 (9.1%)	3 (10.7%)	
Progressive Disease (PD)	4 (18.2%)	7 (25.0%)	
Not Evaluable	5 (22.7%)	9 (32.1%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Age group			
ORR Relative Risk Cochran's Q p-value			0.1416
CBR Relative Risk Cochran's Q p-value			0.9576
Age group: < 65 years	158	161	
Objective Response (CR or PR)			
n (%)	37 (23.4%)	23 (14.3%)	
95% CI (Exact)	(17.1, 30.8)	(9.3, 20.7)	
Odds Ratio			1.835
95% CI (Exact)			(1.033, 3.260)
P-value			0.0372
Relative Risk			1.639
95% CI (Exact)			(1.023, 2.628)
P-value			0.0372
Risk Difference			0.091
95% CI (Wald)			(0.006, 0.177)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Age group: < 65 years	158	161	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	54 (34.2%)	39 (24.2%)	
95% CI (Exact)	(26.8, 42.1)	(17.8, 31.6)	
Odds Ratio			1.624
95% CI (Exact)			(0.997, 2.646)
P-value			0.0509
Relative Risk			1.411
95% CI (Exact)			(0.996, 1.999)
P-value			0.0509
Risk Difference			0.100
95% CI (Wald)			(0.000, 0.199)
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.3%)	0	
Partial Response (PR)	35 (22.2%)	23 (14.3%)	
Stable Disease (SD)	73 (46.2%)	62 (38.5%)	
SD >= 6 months	17 (10.8%)	16 (9.9%)	
Progressive Disease (PD)	41 (25.9%)	46 (28.6%)	
Not Evaluable	7 (4.4%)	30 (18.6%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Age group: >= 65 years	47	52	
Objective Response (CR or PR)			
n (%)	6 (12.8%)	9 (17.3%)	
95% CI (Exact)	(4.8, 25.7)	(8.2, 30.3)	
Odds Ratio			0.699
95% CI (Exact)			(0.229, 2.139)
P-value			0.5312
Relative Risk			0.738
95% CI (Exact)			(0.284, 1.916)
P-value			0.5312
Risk Difference			-0.045
95% CI (Wald)			(-0.186, 0.095)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Age group: >= 65 years	47	52	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	15 (31.9%)	12 (23.1%)	
95% CI (Exact)	(19.1, 47.1)	(12.5, 36.8)	
Odds Ratio			1.563
95% CI (Exact)			(0.642, 3.805)
P-value			0.3266
Relative Risk			1.383
95% CI (Exact)			(0.723, 2.645)
P-value			0.3266
Risk Difference			0.088
95% CI (Wald)			(-0.087, 0.264)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	6 (12.8%)	9 (17.3%)	
Stable Disease (SD)	28 (59.6%)	21 (40.4%)	
SD >= 6 months	9 (19.1%)	3 (5.8%)	
Progressive Disease (PD)	7 (14.9%)	12 (23.1%)	
Not Evaluable	6 (12.8%)	10 (19.2%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Race			
ORR Relative Risk Cochran's Q p-value			0.9246
CBR Relative Risk Cochran's Q p-value			0.5285
Race: White	143	143	
Objective Response (CR or PR)			
n (%)	31 (21.7%)	22 (15.4%)	
95% CI (Exact)	(15.2, 29.3)	(9.9, 22.4)	
Odds Ratio			1.522
95% CI (Exact)			(0.832, 2.784)
P-value			0.1715
Relative Risk			1.409
95% CI (Exact)			(0.859, 2.311)
P-value			0.1715
Risk Difference			0.063
95% CI (Wald)			(-0.027, 0.153)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Race: White	143	143	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	51 (35.7%)	34 (23.8%)	
95% CI (Exact)	(27.8, 44.1)	(17.1, 31.6)	
Odds Ratio			1.777
95% CI (Exact)			(1.062, 2.975)
P-value			0.0281
Relative Risk			1.500
95% CI (Exact)			(1.039, 2.165)
P-value			0.0281
Risk Difference			0.119
95% CI (Wald)			(0.014, 0.224)
Best Overall Response, n (%)			
Complete Response (CR)	1 (0.7%)	0	
Partial Response (PR)	30 (21.0%)	22 (15.4%)	
Stable Disease (SD)	69 (48.3%)	58 (40.6%)	
SD >= 6 months	20 (14.0%)	12 (8.4%)	
Progressive Disease (PD)	34 (23.8%)	36 (25.2%)	
Not Evaluable	9 (6.3%)	27 (18.9%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Race: Non-white	14	18	
Objective Response (CR or PR)			
n (%)	2 (14.3%)	2 (11.1%)	
95% CI (Exact)	(1.8, 42.8)	(1.4, 34.7)	
Odds Ratio			1.333
95% CI (Exact)			(0.164, 10.867)
P-value			0.7909
Relative Risk			1.286
95% CI (Exact)			(0.206, 8.025)
P-value			0.7909
Risk Difference			0.032
95% CI (Wald)			(-0.202, 0.266)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Race: Non-white	14	18	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	3 (21.4%)	4 (22.2%)	
95% CI (Exact)	(4.7, 50.8)	(6.4, 47.6)	
Odds Ratio			0.955
95% CI (Exact)			(0.176, 5.186)
P-value			0.9577
Relative Risk			0.964
95% CI (Exact)			(0.257, 3.624)
P-value			0.9577
Risk Difference			-0.008
95% CI (Wald)			(-0.296, 0.280)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	2 (14.3%)	2 (11.1%)	
Stable Disease (SD)	6 (42.9%)	5 (27.8%)	
SD >= 6 months	1 (7.1%)	2 (11.1%)	
Progressive Disease (PD)	5 (35.7%)	8 (44.4%)	
Not Evaluable	1 (7.1%)	3 (16.7%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Screening ECOG Status			
ORR Relative Risk Cochran's Q p-value			0.5156
CBR Relative Risk Cochran's Q p-value			0.2934
Screening ECOG Status: 0	90	99	
Objective Response (CR or PR)			
n (%)	22 (24.4%)	15 (15.2%)	
95% CI (Exact)	(16.0, 34.6)	(8.7, 23.8)	
Odds Ratio			1.812
95% CI (Exact)			(0.873, 3.760)
P-value			0.1088
Relative Risk			1.613
95% CI (Exact)			(0.893, 2.913)
P-value			0.1088
Risk Difference			0.093
95% CI (Wald)			(-0.021, 0.206)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Screening ECOG Status: 0	90	99	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	35 (38.9%)	23 (23.2%)	
95% CI (Exact)	(28.8, 49.7)	(15.3, 32.8)	
Odds Ratio			2.103
95% CI (Exact)			(1.120, 3.949)
P-value			0.0201
Relative Risk			1.674
95% CI (Exact)			(1.076, 2.604)
P-value			0.0201
Risk Difference			0.157
95% CI (Wald)			(0.026, 0.287)
Best Overall Response, n (%)			
Complete Response (CR)	2 (2.2%)	0	
Partial Response (PR)	20 (22.2%)	15 (15.2%)	
Stable Disease (SD)	44 (48.9%)	36 (36.4%)	
SD >= 6 months	13 (14.4%)	8 (8.1%)	
Progressive Disease (PD)	19 (21.1%)	31 (31.3%)	
Not Evaluable	5 (5.6%)	17 (17.2%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Screening ECOG Status: 1	115	114	
Objective Response (CR or PR)			
n (%)	21 (18.3%)	17 (14.9%)	
95% CI (Exact)	(11.7, 26.5)	(8.9, 22.8)	
Odds Ratio			1.275
95% CI (Exact)			(0.633, 2.566)
P-value			0.4968
Relative Risk			1.225
95% CI (Exact)			(0.682, 2.197)
P-value			0.4968
Risk Difference			0.033
95% CI (Wald)			(-0.063, 0.130)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Screening ECOG Status: 1	115	114	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	34 (29.6%)	28 (24.6%)	
95% CI (Exact)	(21.4, 38.8)	(17.0, 33.5)	
Odds Ratio			1.289
95% CI (Exact)			(0.718, 2.314)
P-value			0.3952
Relative Risk			1.204
95% CI (Exact)			(0.785, 1.847)
P-value			0.3952
Risk Difference			0.050
95% CI (Wald)			(-0.065, 0.165)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	21 (18.3%)	17 (14.9%)	
Stable Disease (SD)	57 (49.6%)	47 (41.2%)	
SD >= 6 months	13 (11.3%)	11 (9.6%)	
Progressive Disease (PD)	29 (25.2%)	27 (23.7%)	
Not Evaluable	8 (7.0%)	23 (20.2%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Geographic Region			
ORR Relative Risk Cochran's Q p-value			0.7861
CBR Relative Risk Cochran's Q p-value			0.4086
Geographic Region: Europe	125	130	
Objective Response (CR or PR)			
n (%)	32 (25.6%)	23 (17.7%)	
95% CI (Exact)	(18.2, 34.2)	(11.6, 25.4)	
Odds Ratio			1.601
95% CI (Exact)			(0.875, 2.927)
P-value			0.1256
Relative Risk			1.447
95% CI (Exact)			(0.899, 2.330)
P-value			0.1256
Risk Difference			0.079
95% CI (Wald)			(-0.022, 0.180)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Geographic Region: Europe	**125**	**130**	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	43 (34.4%)	35 (26.9%)	
95% CI (Exact)	(26.1, 43.4)	(19.5, 35.4)	
Odds Ratio			1.423
95% CI (Exact)			(0.833, 2.431)
P-value			0.1961
Relative Risk			1.278
95% CI (Exact)			(0.880, 1.855)
P-value			0.1961
Risk Difference			0.075
95% CI (Wald)			(-0.038, 0.188)
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.6%)	0	
Partial Response (PR)	30 (24.0%)	23 (17.7%)	
Stable Disease (SD)	54 (43.2%)	52 (40.0%)	
SD >= 6 months	11 (8.8%)	12 (9.2%)	
Progressive Disease (PD)	32 (25.6%)	38 (29.2%)	
Not Evaluable	7 (5.6%)	17 (13.1%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Geographic Region: North America	**80**	**83**	
Objective Response (CR or PR)			
n (%)	**11 (13.8%)**	**9 (10.8%)**	
95% CI (Exact)	**(7.1, 23.3)**	**(5.1, 19.6)**	
Odds Ratio			**1.311**
95% CI (Exact)			**(0.512, 3.356)**
P-value			**0.5730**
Relative Risk			**1.268**
95% CI (Exact)			**(0.555, 2.896)**
P-value			**0.5730**
Risk Difference			**0.029**
95% CI (Wald)			**(-0.072, 0.130)**

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Geographic Region: North America	**80**	**83**	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	**26 (32.5%)**	**16 (19.3%)**	
95% CI (Exact)	**(22.4, 43.9)**	**(11.4, 29.4)**	
Odds Ratio			**2.016**
95% CI (Exact)			**(0.983, 4.136)**
P-value			**0.0544**
Relative Risk			**1.686**
95% CI (Exact)			**(0.981, 2.898)**
P-value			**0.0544**
Risk Difference			**0.132**
95% CI (Wald)			**(-0.001, 0.265)**
Best Overall Response, n (%)			
Complete Response (CR)	**0**	**0**	
Partial Response (PR)	**11 (13.8%)**	**9 (10.8%)**	
Stable Disease (SD)	**47 (58.8%)**	**31 (37.3%)**	
SD >= 6 months	**15 (18.8%)**	**7 (8.4%)**	
Progressive Disease (PD)	**16 (20.0%)**	**20 (24.1%)**	
Not Evaluable	**6 (7.5%)**	**23 (27.7%)**	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Prior CDK treatment duration			
ORR Relative Risk Cochran's Q p-value			0.2029
CBR Relative Risk Cochran's Q p-value			0.0728
Prior CDK treatment duration: <= 12 months	118	128	
Objective Response (CR or PR)			
n (%)	29 (24.6%)	18 (14.1%)	
95% CI (Exact)	(17.1, 33.4)	(8.6, 21.3)	
Odds Ratio			1.991
95% CI (Exact)			(1.038, 3.819)
P-value			0.0365
Relative Risk			1.748
95% CI (Exact)			(1.026, 2.976)
P-value			0.0365
Risk Difference			0.105
95% CI (Wald)			(0.007, 0.203)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Prior CDK treatment duration: <= 12 months	118	128	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	46 (39.0%)	28 (21.9%)	
95% CI (Exact)	(30.1, 48.4)	(15.1, 30.0)	
Odds Ratio			2.282
95% CI (Exact)			(1.305, 3.991)
P-value			0.0035
Relative Risk			1.782
95% CI (Exact)			(1.197, 2.652)
P-value			0.0035
Risk Difference			0.171
95% CI (Wald)			(0.058, 0.285)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	29 (24.6%)	18 (14.1%)	
Stable Disease (SD)	54 (45.8%)	49 (38.3%)	
SD >= 6 months	17 (14.4%)	10 (7.8%)	
Progressive Disease (PD)	26 (22.0%)	39 (30.5%)	
Not Evaluable	9 (7.6%)	22 (17.2%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Prior CDK treatment duration: > 12 months	82	82	
Objective Response (CR or PR)			
n (%)	14 (17.1%)	14 (17.1%)	
95% CI (Exact)	(9.7, 27.0)	(9.7, 27.0)	
Odds Ratio			1.000
95% CI (Exact)			(0.443, 2.256)
P-value			1.0000
Relative Risk			1.000
95% CI (Exact)			(0.509, 1.963)
P-value			1.0000
Risk Difference			0.000
95% CI (Wald)			(-0.115, 0.115)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Prior CDK treatment duration: > 12 months	82	82	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	23 (28.0%)	23 (28.0%)	
95% CI (Exact)	(18.7, 39.1)	(18.7, 39.1)	
Odds Ratio			1.000
95% CI (Exact)			(0.506, 1.977)
P-value			1.0000
Relative Risk			1.000
95% CI (Exact)			(0.612, 1.633)
P-value			1.0000
Risk Difference			0.000
95% CI (Wald)			(-0.138, 0.138)
Best Overall Response, n (%)			
Complete Response (CR)	2 (2.4%)	0	
Partial Response (PR)	12 (14.6%)	14 (17.1%)	
Stable Disease (SD)	45 (54.9%)	33 (40.2%)	
SD >= 6 months	9 (11.0%)	9 (11.0%)	
Progressive Disease (PD)	20 (24.4%)	18 (22.0%)	
Not Evaluable	3 (3.7%)	17 (20.7%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Early relapse			
ORR Relative Risk Cochran's Q p-value			0.0635
CBR Relative Risk Cochran's Q p-value			0.0502
Early relapse: Yes	13	17	
Objective Response (CR or PR)			
n (%)	6 (46.2%)	1 (5.9%)	
95% CI (Exact)	(19.2, 74.9)	(0.1, 28.7)	
Odds Ratio			13.714
95% CI (Exact)			(1.381, 136.212)
P-value			0.0111
Relative Risk			7.846
95% CI (Exact)			(1.072, 57.401)
P-value			0.0111
Risk Difference			0.403
95% CI (Wald)			(0.110, 0.696)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Early relapse: Yes	13	17	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	7 (53.8%)	1 (5.9%)	
95% CI (Exact)	(25.1, 80.8)	(0.1, 28.7)	
Odds Ratio			18.667
95% CI (Exact)			(1.879, 185.399)
P-value			0.0038
Relative Risk			9.154
95% CI (Exact)			(1.281, 65.437)
P-value			0.0038
Risk Difference			0.480
95% CI (Wald)			(0.186, 0.773)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	6 (46.2%)	1 (5.9%)	
Stable Disease (SD)	6 (46.2%)	1 (5.9%)	
SD >= 6 months	1 (7.7%)	0	
Progressive Disease (PD)	1 (7.7%)	10 (58.8%)	
Not Evaluable	0	5 (29.4%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Early relapse: No	185	192	
Objective Response (CR or PR)			
n (%)	34 (18.4%)	31 (16.1%)	
95% CI (Exact)	(13.1, 24.7)	(11.2, 22.1)	
Odds Ratio			1.169
95% CI (Exact)			(0.685, 1.997)
P-value			0.5667
Relative Risk			1.138
95% CI (Exact)			(0.731, 1.772)
P-value			0.5667
Risk Difference			0.022
95% CI (Wald)			(-0.054, 0.099)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Early relapse: No	185	192	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	59 (31.9%)	49 (25.5%)	
95% CI (Exact)	(25.2, 39.1)	(19.5, 32.3)	
Odds Ratio			1.367
95% CI (Exact)			(0.873, 2.139)
P-value			0.1719
Relative Risk			1.250
95% CI (Exact)			(0.907, 1.722)
P-value			0.1719
Risk Difference			0.064
95% CI (Wald)			(-0.027, 0.155)
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.1%)	0	
Partial Response (PR)	32 (17.3%)	31 (16.1%)	
Stable Disease (SD)	92 (49.7%)	79 (41.1%)	
SD >= 6 months	25 (13.5%)	18 (9.4%)	
Progressive Disease (PD)	46 (24.9%)	47 (24.5%)	
Not Evaluable	13 (7.0%)	35 (18.2%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR)			
ORR Relative Risk Cochran's Q p-value			0.3104
CBR Relative Risk Cochran's Q p-value			0.3014
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes	181	187	
Objective Response (CR or PR)			
n (%)	36 (19.9%)	29 (15.5%)	
95% CI (Exact)	(14.3, 26.5)	(10.6, 21.5)	
Odds Ratio			1.353
95% CI (Exact)			(0.789, 2.318)
P-value			0.2712
Relative Risk			1.283
95% CI (Exact)			(0.822, 2.000)
P-value			0.2712
Risk Difference			0.044
95% CI (Wald)			(-0.034, 0.122)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes	181	187	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	56 (30.9%)	44 (23.5%)	
95% CI (Exact)	(24.3, 38.2)	(17.6, 30.3)	
Odds Ratio			1.456
95% CI (Exact)			(0.917, 2.311)
P-value			0.1107
Relative Risk			1.315
95% CI (Exact)			(0.938, 1.843)
P-value			0.1107
Risk Difference			0.074
95% CI (Wald)			(-0.017, 0.165)
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.1%)	0	
Partial Response (PR)	34 (18.8%)	29 (15.5%)	
Stable Disease (SD)	87 (48.1%)	74 (39.6%)	
SD >= 6 months	20 (11.0%)	15 (8.0%)	
Progressive Disease (PD)	45 (24.9%)	49 (26.2%)	
Not Evaluable	13 (7.2%)	35 (18.7%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No	24	26	
Objective Response (CR or PR)			
n (%)	7 (29.2%)	3 (11.5%)	
95% CI (Exact)	(12.6, 51.1)	(2.4, 30.2)	
Odds Ratio			3.157
95% CI (Exact)			(0.711, 14.017)
P-value			0.1233
Relative Risk			2.528
95% CI (Exact)			(0.736, 8.678)
P-value			0.1233
Risk Difference			0.176
95% CI (Wald)			(-0.043, 0.396)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No	24	26	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	13 (54.2%)	7 (26.9%)	
95% CI (Exact)	(32.8, 74.4)	(11.6, 47.8)	
Odds Ratio			3.208
95% CI (Exact)			(0.984, 10.454)
P-value			0.0518
Relative Risk			2.012
95% CI (Exact)			(0.967, 4.185)
P-value			0.0518
Risk Difference			0.272
95% CI (Wald)			(0.010, 0.535)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	7 (29.2%)	3 (11.5%)	
Stable Disease (SD)	14 (58.3%)	9 (34.6%)	
SD >= 6 months	6 (25.0%)	4 (15.4%)	
Progressive Disease (PD)	3 (12.5%)	9 (34.6%)	
Not Evaluable	0	5 (19.2%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Chemotherapy in neo/adjuvant setting			
ORR Relative Risk Cochran's Q p-value			0.0243
CBR Relative Risk Cochran's Q p-value			0.0756
Chemotherapy in neo/adjuvant setting: Yes	125	145	
Objective Response (CR or PR)			
n (%)	31 (24.8%)	18 (12.4%)	
95% CI (Exact)	(17.5, 33.3)	(7.5, 18.9)	
Odds Ratio			2.327
95% CI (Exact)			(1.228, 4.409)
P-value			0.0086
Relative Risk			1.998
95% CI (Exact)			(1.177, 3.392)
P-value			0.0086
Risk Difference			0.124
95% CI (Wald)			(0.031, 0.217)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Chemotherapy in neo/adjuvant setting: Yes	125	145	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	42 (33.6%)	28 (19.3%)	
95% CI (Exact)	(25.4, 42.6)	(13.2, 26.7)	
Odds Ratio			2.114
95% CI (Exact)			(1.214, 3.682)
P-value			0.0077
Relative Risk			1.740
95% CI (Exact)			(1.150, 2.632)
P-value			0.0077
Risk Difference			0.143
95% CI (Wald)			(0.038, 0.248)
Best Overall Response, n (%)			
Complete Response (CR)	2 (1.6%)	0	
Partial Response (PR)	29 (23.2%)	18 (12.4%)	
Stable Disease (SD)	62 (49.6%)	52 (35.9%)	
SD >= 6 months	11 (8.8%)	10 (6.9%)	
Progressive Disease (PD)	25 (20.0%)	42 (29.0%)	
Not Evaluable	7 (5.6%)	33 (22.8%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Chemotherapy in neo/adjuvant setting: No	80	68	
Objective Response (CR or PR)			
n (%)	12 (15.0%)	14 (20.6%)	
95% CI (Exact)	(8.0, 24.7)	(11.7, 32.1)	
Odds Ratio			0.681
95% CI (Exact)			(0.291, 1.592)
P-value			0.3749
Relative Risk			0.729
95% CI (Exact)			(0.362, 1.467)
P-value			0.3749
Risk Difference			-0.056
95% CI (Wald)			(-0.180, 0.068)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Chemotherapy in neo/adjuvant setting: No	80	68	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	27 (33.8%)	23 (33.8%)	
95% CI (Exact)	(23.6, 45.2)	(22.8, 46.3)	
Odds Ratio			0.997
95% CI (Exact)			(0.503, 1.974)
P-value			0.9925
Relative Risk			0.998
95% CI (Exact)			(0.635, 1.569)
P-value			0.9925
Risk Difference			-0.001
95% CI (Wald)			(-0.154, 0.152)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	12 (15.0%)	14 (20.6%)	
Stable Disease (SD)	39 (48.8%)	31 (45.6%)	
SD >= 6 months	15 (18.8%)	9 (13.2%)	
Progressive Disease (PD)	23 (28.8%)	16 (23.5%)	
Not Evaluable	6 (7.5%)	7 (10.3%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Trop2			
ORR Relative Risk Cochran's Q p-value			0.2529
CBR Relative Risk Cochran's Q p-value			0.0912
Trop2: H-Score < 100	68	73	
Objective Response (CR or PR)			
n (%)	14 (20.6%)	16 (21.9%)	
95% CI (Exact)	(11.7, 32.1)	(13.1, 33.1)	
Odds Ratio			0.924
95% CI (Exact)			(0.412, 2.072)
P-value			0.8477
Relative Risk			0.939
95% CI (Exact)			(0.497, 1.776)
P-value			0.8477
Risk Difference			-0.013
95% CI (Wald)			(-0.148, 0.122)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Trop2: H-Score < 100	68	73	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	19 (27.9%)	22 (30.1%)	
95% CI (Exact)	(17.7, 40.1)	(19.9, 42.0)	
Odds Ratio			0.899
95% CI (Exact)			(0.434, 1.862)
P-value			0.7750
Relative Risk			0.927
95% CI (Exact)			(0.553, 1.555)
P-value			0.7750
Risk Difference			-0.022
95% CI (Wald)			(-0.172, 0.128)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	14 (20.6%)	16 (21.9%)	
Stable Disease (SD)	34 (50.0%)	27 (37.0%)	
SD >= 6 months	5 (7.4%)	6 (8.2%)	
Progressive Disease (PD)	15 (22.1%)	21 (28.8%)	
Not Evaluable	5 (7.4%)	9 (12.3%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Trop2: H-Score >= 100 and <= 200	71	78	
Objective Response (CR or PR)			
n (%)	17 (23.9%)	9 (11.5%)	
95% CI (Exact)	(14.6, 35.5)	(5.4, 20.8)	
Odds Ratio			2.414
95% CI (Exact)			(0.998, 5.836)
P-value			0.0470
Relative Risk			2.075
95% CI (Exact)			(0.989, 4.355)
P-value			0.0470
Risk Difference			0.124
95% CI (Wald)			(0.002, 0.246)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Trop2: H-Score >= 100 and <= 200	71	78	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	27 (38.0%)	15 (19.2%)	
95% CI (Exact)	(26.8, 50.3)	(11.2, 29.7)	
Odds Ratio			2.577
95% CI (Exact)			(1.230, 5.398)
P-value			0.0111
Relative Risk			1.977
95% CI (Exact)			(1.149, 3.404)
P-value			0.0111
Risk Difference			0.188
95% CI (Wald)			(0.045, 0.331)
Best Overall Response, n (%)			
Complete Response (CR)	1 (1.4%)	0	
Partial Response (PR)	16 (22.5%)	9 (11.5%)	
Stable Disease (SD)	35 (49.3%)	25 (32.1%)	
SD >= 6 months	10 (14.1%)	6 (7.7%)	
Progressive Disease (PD)	17 (23.9%)	30 (38.5%)	
Not Evaluable	2 (2.8%)	14 (17.9%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Trop2: H-Score > 200	42	26	
Objective Response (CR or PR)			
n (%)	10 (23.8%)	6 (23.1%)	
95% CI (Exact)	(12.1, 39.5)	(9.0, 43.6)	
Odds Ratio			1.042
95% CI (Exact)			(0.328, 3.310)
P-value			0.9452
Relative Risk			1.032
95% CI (Exact)			(0.425, 2.503)
P-value			0.9452
Risk Difference			0.007
95% CI (Wald)			(-0.200, 0.214)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Trop2: H-Score > 200	42	26	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	17 (40.5%)	11 (42.3%)	
95% CI (Exact)	(25.6, 56.7)	(23.4, 63.1)	
Odds Ratio			0.927
95% CI (Exact)			(0.344, 2.502)
P-value			0.8823
Relative Risk			0.957
95% CI (Exact)			(0.536, 1.708)
P-value			0.8823
Risk Difference			-0.018
95% CI (Wald)			(-0.259, 0.223)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	10 (23.8%)	6 (23.1%)	
Stable Disease (SD)	14 (33.3%)	16 (61.5%)	
SD >= 6 months	7 (16.7%)	5 (19.2%)	
Progressive Disease (PD)	14 (33.3%)	3 (11.5%)	
Not Evaluable	4 (9.5%)	1 (3.8%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Subgroup: Investigators' Choice of Chemotherapy			
ORR Relative Risk Cochran's Q p-value			0.0173
CBR Relative Risk Cochran's Q p-value			0.0024
Investigators' Choice of Chemotherapy: Capecitabine	21	23	
Objective Response (CR or PR)			
n (%)	2 (9.5%)	6 (26.1%)	
95% CI (Exact)	(1.2, 30.4)	(10.2, 48.4)	
Odds Ratio			0.298
95% CI (Exact)			(0.053, 1.680)
P-value			0.1596
Relative Risk			0.365
95% CI (Exact)			(0.083, 1.615)
P-value			0.1596
Risk Difference			-0.166
95% CI (Wald)			(-0.385, 0.053)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Gilead Sciences, Inc.
Study IMMU-132-09

Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Investigators' Choice of Chemotherapy: Capecitabine	21	23	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	3 (14.3%)	8 (34.8%)	
95% CI (Exact)	(3.0, 36.3)	(16.4, 57.3)	
Odds Ratio			0.313
95% CI (Exact)			(0.070, 1.391)
P-value			0.1210
Relative Risk			0.411
95% CI (Exact)			(0.125, 1.347)
P-value			0.1210
Risk Difference			-0.205
95% CI (Wald)			(-0.451, 0.041)
Best Overall Response, n (%)			
Complete Response (CR)	0	0	
Partial Response (PR)	2 (9.5%)	6 (26.1%)	
Stable Disease (SD)	11 (52.4%)	9 (39.1%)	
SD >= 6 months	1 (4.8%)	2 (8.7%)	
Progressive Disease (PD)	8 (38.1%)	6 (26.1%)	
Not Evaluable	0	2 (8.7%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Investigators' Choice of Chemotherapy: Eribulin	128	130	
Objective Response (CR or PR)			
n (%)	28 (21.9%)	24 (18.5%)	
95% CI (Exact)	(15.1, 30.0)	(12.2, 26.2)	
Odds Ratio			1.237
95% CI (Exact)			(0.672, 2.276)
P-value			0.4952
Relative Risk			1.185
95% CI (Exact)			(0.728, 1.929)
P-value			0.4952
Risk Difference			0.034
95% CI (Wald)			(-0.064, 0.132)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Gilead Sciences, Inc.
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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Investigators' Choice of Chemotherapy: Eribulin	128	130	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	45 (35.2%)	39 (30.0%)	
95% CI (Exact)	(26.9, 44.1)	(22.3, 38.7)	
Odds Ratio			1.265
95% CI (Exact)			(0.751, 2.132)
P-value			0.3778
Relative Risk			1.172
95% CI (Exact)			(0.824, 1.667)
P-value			0.3778
Risk Difference			0.052
95% CI (Wald)			(-0.063, 0.166)
Best Overall Response, n (%)			
Complete Response (CR)	1 (0.8%)	0	
Partial Response (PR)	27 (21.1%)	24 (18.5%)	
Stable Disease (SD)	64 (50.0%)	58 (44.6%)	
SD >= 6 months	17 (13.3%)	15 (11.5%)	
Progressive Disease (PD)	27 (21.1%)	28 (21.5%)	
Not Evaluable	9 (7.0%)	20 (15.4%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Investigators' Choice of Chemotherapy: Vinorelbine	56	60	
Objective Response (CR or PR)			
n (%)	13 (23.2%)	2 (3.3%)	
95% CI (Exact)	(13.0, 36.4)	(0.4, 11.5)	
Odds Ratio			8.767
95% CI (Exact)			(1.879, 40.899)
P-value			0.0015
Relative Risk			6.964
95% CI (Exact)			(1.644, 29.496)
P-value			0.0015
Risk Difference			0.199
95% CI (Wald)			(0.079, 0.318)

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.2.3.2: Objective Response Rate (ORR), Clinical Benefit Rate (CBR) per BICR by Selected Subgroup
ITT Population
Excluding participants pre-selected to Gemcitabine

	SG (N=205)	TPC (N=213)	Treatment Comparison
Investigators' Choice of Chemotherapy: Vinorelbine	56	60	
Clinical Benefit Rate (CR, PR, or SD >= 6 months)			
n (%)	21 (37.5%)	4 (6.7%)	
95% CI (Exact)	(24.9, 51.5)	(1.8, 16.2)	
Odds Ratio			8.400
95% CI (Exact)			(2.661, 26.519)
P-value			<0.0001
Relative Risk			5.625
95% CI (Exact)			(2.058, 15.372)
P-value			<0.0001
Risk Difference			0.308
95% CI (Wald)			(0.167, 0.450)
Best Overall Response, n (%)			
Complete Response (CR)	1 (1.8%)	0	
Partial Response (PR)	12 (21.4%)	2 (3.3%)	
Stable Disease (SD)	26 (46.4%)	16 (26.7%)	
SD >= 6 months	8 (14.3%)	2 (3.3%)	
Progressive Disease (PD)	13 (23.2%)	24 (40.0%)	
Not Evaluable	4 (7.1%)	18 (30.0%)	

The denominator is the number of patients in the ITT excluding those pre-assigned to Gemcitabine for each treatment arm per category in each subgroup.
Odds ratio and relative risk CIs and p-values are from unstratified CMH method, risk difference CI is from Wald method.
The best overall response is derived based on the tumor response per BICR at each tumor assessment according to RECIST 1.1. Response of CR
Clinical benefit rate (CBR) is the proportion of participants who have best confirmed response as CR/PR or durable SD with duration >= 6 months
The analysis is based on Interim 2 data cut at 7/1/2022.

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Anhang 4-G 6: Patientenberichtete Endpunkte

Anhang 4-G 6.1: Rücklauf

Table 15.15.2.1
Completion Rate for EORTC QLQ-C30
Intent-to-Treat Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=205)	TPC (N=213)	Overall (N=418)
Baseline	187/205 (91.2%)	184/213 (86.4%)	371/418 (88.8%)
C2D1	162/186 (87.1%)	152/176 (86.4%)	314/362 (86.7%)
C3D1	134/146 (91.8%)	107/121 (88.4%)	241/267 (90.3%)
C4D1	120/134 (89.6%)	99/109 (90.8%)	219/243 (90.1%)
C5D1	107/121 (88.4%)	85/94 (90.4%)	192/215 (89.3%)
C6D1	103/112 (92.0%)	73/84 (86.9%)	176/196 (89.8%)
C7D1	86/94 (91.5%)	55/59 (93.2%)	141/153 (92.2%)
C8D1	81/89 (91.0%)	51/53 (96.2%)	132/142 (93.0%)
C9D1	65/71 (91.5%)	43/44 (97.7%)	108/115 (93.9%)
C10D1	58/62 (93.5%)	31/37 (83.8%)	89/99 (89.9%)
C11D1	49/52 (94.2%)	24/28 (85.7%)	73/80 (91.3%)
C12D1	44/48 (91.7%)	20/23 (87.0%)	64/71 (90.1%)
C13D1	36/39 (92.3%)	16/17 (94.1%)	52/56 (92.9%)
C14D1	35/36 (97.2%)	13/16 (81.3%)	48/52 (92.3%)
C15D1	30/33 (90.9%)	14/16 (87.5%)	44/49 (89.8%)
C16D1	30/31 (96.8%)	11/13 (84.6%)	41/44 (93.2%)
C17D1	28/29 (96.6%)	7/10 (70.0%)	35/39 (89.7%)
C18D1	23/25 (92.0%)	7/7 (100.0%)	30/32 (93.8%)
C19D1	21/23 (91.3%)	6/6 (100.0%)	27/29 (93.1%)
C20D1	20/20 (100.0%)	4/4 (100.0%)	24/24 (100.0%)

Note: "Intent-to-Treat Population" is defined as all randomized subjects. A subject is considered having an evaluable assessment of EORTC QLQ-C30 if at least one of the 15 domains/scales were completed at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of ITT population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of ITT population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of ITT population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit.
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.2.1
Completion Rate for EORTC QLQ-C30
Intent-to-Treat Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=205)	TPC (N=213)	Overall (N=418)
C21D1	18/19 (94.7%)	4/4 (100.0%)	22/23 (95.7%)
C22D1	15/16 (93.8%)	3/3 (100.0%)	18/19 (94.7%)
C23D1	11/12 (91.7%)	3/3 (100.0%)	14/15 (93.3%)
C24D1	10/10 (100.0%)	2/2 (100.0%)	12/12 (100.0%)
C25D1	9/10 (90.0%)	0/1 (0.0%)	9/11 (81.8%)
C26D1	8/8 (100.0%)	1/1 (100.0%)	9/9 (100.0%)
C27D1	8/8 (100.0%)	1/1 (100.0%)	9/9 (100.0%)
C28D1	7/7 (100.0%)	1/1 (100.0%)	8/8 (100.0%)
C29D1	4/5 (80.0%)	1/1 (100.0%)	5/6 (83.3%)
C30D1	4/4 (100.0%)	1/1 (100.0%)	5/5 (100.0%)
C31D1	2/3 (66.7%)	1/1 (100.0%)	3/4 (75.0%)
C32D1	2/3 (66.7%)	1/1 (100.0%)	3/4 (75.0%)
C33D1	3/3 (100.0%)	1/1 (100.0%)	4/4 (100.0%)
C34D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C35D1	2/3 (66.7%)	0/0 (NE)	2/3 (66.7%)
C36D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C37D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C38D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C39D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C40D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)

Note: "Intent-to-Treat Population" is defined as all randomized subjects. A subject is considered having an evaluable assessment of EORTC QLQ-C30 if at least one of the 15 domains/scales were completed at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of ITT population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of ITT population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of ITT population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit.
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
Source: ADSL ADQS ADEX TPCCHOICE Program Name: t_compliance.sas Date Generated: 17MAY2023 Page 2 of 9

Table 15.15.2.1
Completion Rate for EORTC QLQ-C30
Intent-to-Treat Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=205)	TPC (N=213)	Overall (N=418)
C41D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C42D1	1/1 (100.0%)	0/0 (NE)	1/1 (100.0%)
C43D1	1/1 (100.0%)	0/0 (NE)	1/1 (100.0%)
End of Treatment	138/169 (81.7%)	132/166 (79.5%)	270/335 (80.6%)

Note: "Intent-to-Treat Population" is defined as all randomized subjects. A subject is considered having an evaluable assessment of EORTC QLQ-C30 if at least one of the 15 domains/scales were completed at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of ITT population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of ITT population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of ITT population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit.
EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.2.2
Completion Rate for EQ-5D VAS
Intent-to-Treat Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=205)	TPC (N=213)	Overall (N=418)
Baseline	182/205 (88.8%)	182/213 (85.4%)	364/418 (87.1%)
C2D1	161/186 (86.6%)	150/176 (85.2%)	311/362 (85.9%)
C3D1	135/146 (92.5%)	108/121 (89.3%)	243/267 (91.0%)
C4D1	119/134 (88.8%)	98/109 (89.9%)	217/243 (89.3%)
C5D1	107/121 (88.4%)	84/94 (89.4%)	191/215 (88.8%)
C6D1	103/112 (92.0%)	73/84 (86.9%)	176/196 (89.8%)
C7D1	85/94 (90.4%)	55/59 (93.2%)	140/153 (91.5%)
C8D1	81/89 (91.0%)	50/53 (94.3%)	131/142 (92.3%)
C9D1	65/71 (91.5%)	42/44 (95.5%)	107/115 (93.0%)
C10D1	59/62 (95.2%)	30/37 (81.1%)	89/99 (89.9%)
C11D1	49/52 (94.2%)	24/28 (85.7%)	73/80 (91.3%)
C12D1	43/48 (89.6%)	20/23 (87.0%)	63/71 (88.7%)
C13D1	37/39 (94.9%)	16/17 (94.1%)	53/56 (94.6%)
C14D1	34/36 (94.4%)	13/16 (81.3%)	47/52 (90.4%)
C15D1	30/33 (90.9%)	14/16 (87.5%)	44/49 (89.8%)
C16D1	30/31 (96.8%)	11/13 (84.6%)	41/44 (93.2%)
C17D1	28/29 (96.6%)	7/10 (70.0%)	35/39 (89.7%)
C18D1	23/25 (92.0%)	7/7 (100.0%)	30/32 (93.8%)
C19D1	21/23 (91.3%)	6/6 (100.0%)	27/29 (93.1%)
C20D1	19/20 (95.0%)	4/4 (100.0%)	23/24 (95.8%)
C21D1	18/19 (94.7%)	4/4 (100.0%)	22/23 (95.7%)

Note: "Intent-to-Treat Population" is defined as all randomized subjects. A subject is considered having an evaluable assessment of EQ-VAS if no missing EQ-VAS value at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of ITT population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of ITT population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of ITT population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit. SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

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Table 15.15.2.2
Completion Rate for EQ-5D VAS
Intent-to-Treat Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=205)	TPC (N=213)	Overall (N=418)
C22D1	15/16 (93.8%)	3/3 (100.0%)	18/19 (94.7%)
C23D1	11/12 (91.7%)	3/3 (100.0%)	14/15 (93.3%)
C24D1	10/10 (100.0%)	2/2 (100.0%)	12/12 (100.0%)
C25D1	9/10 (90.0%)	0/1 (0.0%)	9/11 (81.8%)
C26D1	8/8 (100.0%)	1/1 (100.0%)	9/9 (100.0%)
C27D1	8/8 (100.0%)	1/1 (100.0%)	9/9 (100.0%)
C28D1	6/7 (85.7%)	1/1 (100.0%)	7/8 (87.5%)
C29D1	4/5 (80.0%)	1/1 (100.0%)	5/6 (83.3%)
C30D1	4/4 (100.0%)	1/1 (100.0%)	5/5 (100.0%)
C31D1	2/3 (66.7%)	1/1 (100.0%)	3/4 (75.0%)
C32D1	2/3 (66.7%)	1/1 (100.0%)	3/4 (75.0%)
C33D1	2/3 (66.7%)	1/1 (100.0%)	3/4 (75.0%)
C34D1	2/3 (66.7%)	0/0 (NE)	2/3 (66.7%)
C35D1	2/3 (66.7%)	0/0 (NE)	2/3 (66.7%)
C36D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C37D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C38D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C39D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C40D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C41D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)

Note: "Intent-to-Treat Population" is defined as all randomized subjects. A subject is considered having an evaluable assessment of EQ-VAS if no missing EQ-VAS value at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of ITT population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of ITT population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of ITT population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit. SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

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Table 15.15.2.2
Completion Rate for EQ-5D VAS
Intent-to-Treat Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=205)	TPC (N=213)	Overall (N=418)
C42D1	1/1 (100.0%)	0/0 (NE)	1/1 (100.0%)
C43D1	1/1 (100.0%)	0/0 (NE)	1/1 (100.0%)
End of Treatment	135/168 (80.4%)	131/166 (78.9%)	266/334 (79.6%)

Note: "Intent-to-Treat Population" is defined as all randomized subjects. A subject is considered having an evaluable assessment of EQ-VAS if no missing EQ-VAS value at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of ITT population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of ITT population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of ITT population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit. SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
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Table 15.15.2.3
Completion Rate for PRO-CTCAE
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=201)	TPC (N=194)	Overall (N=395)
Baseline	177/201 (88.1%)	180/194 (92.8%)	357/395 (90.4%)
C2D1	163/186 (87.6%)	151/176 (85.8%)	314/362 (86.7%)
C3D1	133/146 (91.1%)	106/121 (87.6%)	239/267 (89.5%)
C4D1	119/134 (88.8%)	97/109 (89.0%)	216/243 (88.9%)
C5D1	106/121 (87.6%)	83/94 (88.3%)	189/215 (87.9%)
C6D1	102/112 (91.1%)	74/84 (88.1%)	176/196 (89.8%)
C7D1	85/94 (90.4%)	56/59 (94.9%)	141/153 (92.2%)
C8D1	80/89 (89.9%)	51/53 (96.2%)	131/142 (92.3%)
C9D1	64/71 (90.1%)	42/44 (95.5%)	106/115 (92.2%)
C10D1	57/62 (91.9%)	31/37 (83.8%)	88/99 (88.9%)
C11D1	49/52 (94.2%)	24/28 (85.7%)	73/80 (91.3%)
C12D1	43/48 (89.6%)	20/23 (87.0%)	63/71 (88.7%)
C13D1	36/39 (92.3%)	15/17 (88.2%)	51/56 (91.1%)
C14D1	35/36 (97.2%)	13/16 (81.3%)	48/52 (92.3%)
C15D1	30/33 (90.9%)	14/16 (87.5%)	44/49 (89.8%)
C16D1	30/31 (96.8%)	11/13 (84.6%)	41/44 (93.2%)
C17D1	28/29 (96.6%)	7/10 (70.0%)	35/39 (89.7%)
C18D1	23/25 (92.0%)	7/7 (100.0%)	30/32 (93.8%)
C19D1	21/23 (91.3%)	6/6 (100.0%)	27/29 (93.1%)
C20D1	20/20 (100.0%)	4/4 (100.0%)	24/24 (100.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. A subject is considered having an evaluable assessment of PRO-CTCAE if at least one of the 16 PRO-CTCAE assessment items were completed at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of safety population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of safety population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of safety population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.2.3
Completion Rate for PRO-CTCAE
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=201)	TPC (N=194)	Overall (N=395)
C21D1	18/19 (94.7%)	4/4 (100.0%)	22/23 (95.7%)
C22D1	15/16 (93.8%)	3/3 (100.0%)	18/19 (94.7%)
C23D1	10/11 (90.9%)	3/3 (100.0%)	13/14 (92.9%)
C24D1	10/10 (100.0%)	2/2 (100.0%)	12/12 (100.0%)
C25D1	9/10 (90.0%)	0/1 (0.0%)	9/11 (81.8%)
C26D1	8/8 (100.0%)	1/1 (100.0%)	9/9 (100.0%)
C27D1	8/8 (100.0%)	1/1 (100.0%)	9/9 (100.0%)
C28D1	7/7 (100.0%)	1/1 (100.0%)	8/8 (100.0%)
C29D1	4/5 (80.0%)	1/1 (100.0%)	5/6 (83.3%)
C30D1	4/4 (100.0%)	1/1 (100.0%)	5/5 (100.0%)
C31D1	2/3 (66.7%)	1/1 (100.0%)	3/4 (75.0%)
C32D1	2/3 (66.7%)	1/1 (100.0%)	3/4 (75.0%)
C33D1	3/3 (100.0%)	1/1 (100.0%)	4/4 (100.0%)
C34D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C35D1	2/3 (66.7%)	0/0 (NE)	2/3 (66.7%)
C36D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C37D1	3/3 (100.0%)	0/0 (NE)	3/3 (100.0%)
C38D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C39D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C40D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. A subject is considered having an evaluable assessment of PRO-CTCAE if at least one of the 16 PRO-CTCAE assessment items were completed at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of safety population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of safety population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of safety population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.2.3
Completion Rate for PRO-CTCAE
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Visit	SG (N=201)	TPC (N=194)	Overall (N=395)
C41D1	2/2 (100.0%)	0/0 (NE)	2/2 (100.0%)
C42D1	1/1 (100.0%)	0/0 (NE)	1/1 (100.0%)
C43D1	1/1 (100.0%)	0/0 (NE)	1/1 (100.0%)
End of Treatment	137/168 (81.5%)	132/166 (79.5%)	269/334 (80.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. A subject is considered having an evaluable assessment of PRO-CTCAE if at least one of the 16 PRO-CTCAE assessment items were completed at a given assessment. The denominator for Cycle 1 Day 1 (C1D1) visit is estimated based on the number of safety population. The denominator for C2D1, C3D1, etc. visits is estimated based on the number of safety population having at least one dose at or after Cycle 2, 3, etc., respectively, or having an valid assessment at that visit. The denominator for EOT visit is estimated based on the number of safety population with treatment discontinuation and still being followed after the date of last dose plus 30 days or having an HRQoL evaluable assessment at the EOT visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Anhang 4-G 6.2: Veränderung zu Baseline

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
Global Health Status / QoL	Baseline	N	174			165		
		Mean	63.9			63.8		
		SD	20.87			19.75		
		Median	66.7			66.7		
		95% CI	60.8, 67.0			60.8, 66.9		
		Q1, Q3	50.0, 83.3			50.0, 75.0		
		Min, Max	8.3, 100.0			8.3, 100.0		
	C2D1	N	152	152	152	144	144	144
		Mean	64.9	63.3	-1.6	64.3	60.9	-3.4
		SD	20.85	21.47	18.79	19.95	20.94	19.25
		Median	66.7	66.7	0.0	66.7	66.7	0.0
		95% CI	61.6, 68.3	59.8, 66.7	-4.7, 1.4	61.0, 67.6	57.4, 64.3	-6.6, -0.2
		Q1, Q3	50.0, 83.3	50.0, 83.3	-8.3, 8.3	50.0, 75.0	50.0, 79.2	-16.7, 8.3
		Min, Max	8.3, 100.0	0.0, 100.0	-83.3, 33.3	8.3, 100.0	0.0, 100.0	-100.0, 58.3
		Mean Diff (95% CI) [a]			-1.6 (-4.7, 1.4)			-3.4 (-6.6, -0.2)
		P-value [a]			0.282			0.035
		Mean Diff (95% CI) [b]			1.8 (-2.6, 6.1)			
		P-value [b]			0.424			
		Effect Size (95% CI) [c]			0.09 (-0.13, 0.30)			
	C3D1	N	123	123	123	100	100	100
		Mean	65.4	65.7	0.2	65.9	64.8	-1.1
		SD	19.87	20.23	18.71	18.43	19.01	16.99
		Median	66.7	66.7	0.0	66.7	66.7	0.0
		95% CI	61.9, 69.0	62.0, 69.3	-3.1, 3.5	62.3, 69.6	61.1, 68.6	-4.5, 2.3
		Q1, Q3	50.0, 83.3	50.0, 83.3	-8.3, 16.7	50.0, 83.3	50.0, 83.3	-16.7, 8.3
		Min, Max	16.7, 100.0	16.7, 100.0	-66.7, 50.0	8.3, 100.0	16.7, 100.0	-33.3, 41.7
		Mean Diff (95% CI) [a]			0.2 (-3.1, 3.5)			-1.1 (-4.5, 2.3)
		P-value [a]			0.904			0.525
		Mean Diff (95% CI) [b]			1.3 (-3.5, 6.1)			
		P-value [b]			0.595			
		Effect Size (95% CI) [c]			0.06 (-0.15, 0.28)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	65.0	68.5	3.5	66.1	66.8	0.6
		SD	19.14	21.42	19.30	18.04	20.28	19.64
		Median	66.7	70.8	0.0	66.7	66.7	0.0
		95% CI	61.4, 68.6	64.5, 72.5	-0.1, 7.1	62.4, 69.8	62.6, 70.9	-3.4, 4.6
		Q1, Q3	50.0, 83.3	50.0, 83.3	-4.2, 16.7	50.0, 83.3	50.0, 83.3	-8.3, 8.3
		Min, Max	16.7, 100.0	0.0, 100.0	-75.0, 50.0	8.3, 100.0	16.7, 100.0	-50.0, 66.7
		Mean Diff (95% CI) [a]			3.5 (-0.1, 7.1)			0.6 (-3.4, 4.6)
		P-value [a]			0.058			0.760
		Mean Diff (95% CI) [b]			2.9 (-2.5, 8.2)			
		P-value [b]			0.292			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.35)			
	C5D1	N	98	98	98	80	80	80
		Mean	65.8	67.9	2.0	65.5	64.3	-1.2
		SD	19.42	19.37	21.07	17.92	19.27	17.50
		Median	66.7	66.7	0.0	66.7	66.7	0.0
		95% CI	61.9, 69.7	64.0, 71.7	-2.2, 6.3	61.5, 69.5	60.0, 68.6	-5.1, 2.6
		Q1, Q3	50.0, 83.3	50.0, 83.3	-8.3, 16.7	50.0, 83.3	50.0, 83.3	-8.3, 8.3
		Min, Max	16.7, 100.0	16.7, 100.0	-66.7, 50.0	8.3, 100.0	16.7, 100.0	-41.7, 58.3
		Mean Diff (95% CI) [a]			2.0 (-2.2, 6.3)			-1.2 (-5.1, 2.6)
		P-value [a]			0.340			0.525
		Mean Diff (95% CI) [b]			3.3 (-2.5, 9.1)			
		P-value [b]			0.265			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	68	68	68
		Mean	67.0	70.7	3.6	65.3	65.9	0.6
		SD	19.38	20.05	18.65	18.30	21.96	18.90
		Median	66.7	70.8	0.0	66.7	66.7	0.0
		95% CI	63.1, 70.9	66.6, 74.7	-0.1, 7.4	60.9, 69.7	60.6, 71.2	-4.0, 5.2
		Q1, Q3	50.0, 83.3	58.3, 83.3	0.0, 16.7	50.0, 83.3	50.0, 83.3	-8.3, 16.7
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	8.3, 100.0	0.0, 100.0	-50.0, 41.7
		Mean Diff (95% CI) [a]			3.6 (-0.1, 7.4)			0.6 (-4.0, 5.2)
		P-value [a]			0.058			0.790
		Mean Diff (95% CI) [b]			3.0 (-2.8, 8.9)			
		P-value [b]			0.309			
		Effect Size (95% CI) [c]			0.15 (-0.06, 0.36)			
	C7D1	N	79	79	79	52	52	52
		Mean	65.4	68.6	3.2	67.9	71.2	3.2
		SD	19.25	19.52	17.62	17.73	17.03	18.54
		Median	66.7	66.7	0.0	75.0	66.7	0.0
		95% CI	61.1, 69.7	64.2, 72.9	-0.8, 7.1	63.0, 72.9	66.4, 75.9	-2.0, 8.4
		Q1, Q3	50.0, 83.3	50.0, 83.3	0.0, 16.7	50.0, 83.3	62.5, 83.3	-8.3, 16.7
		Min, Max	16.7, 100.0	8.3, 100.0	-58.3, 50.0	16.7, 100.0	33.3, 100.0	-50.0, 58.3
		Mean Diff (95% CI) [a]			3.2 (-0.8, 7.1)			3.2 (-2.0, 8.4)
		P-value [a]			0.114			0.218
		Mean Diff (95% CI) [b]			0.0 (-6.4, 6.3)			
		P-value [b]			0.990			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	75	75	75	50	50	50
		Mean	64.9	68.6	3.7	68.5	71.0	2.5
		SD	19.15	19.59	18.34	17.76	16.34	17.44
		Median	66.7	66.7	0.0	75.0	66.7	0.0
		95% CI	60.5, 69.3	64.0, 73.1	-0.6, 7.9	63.5, 73.5	66.4, 75.6	-2.5, 7.5
		Q1, Q3	50.0, 83.3	58.3, 83.3	0.0, 16.7	58.3, 83.3	66.7, 83.3	-8.3, 8.3
		Min, Max	16.7, 100.0	8.3, 100.0	-75.0, 41.7	16.7, 100.0	0.0, 100.0	-50.0, 50.0
		Mean Diff (95% CI) [a]			3.7 (-0.6, 7.9)			2.5 (-2.5, 7.5)
		P-value [a]			0.088			0.316
		Mean Diff (95% CI) [b]			1.2 (-5.3, 7.7)			
		P-value [b]			0.723			
		Effect Size (95% CI) [c]			0.06 (-0.16, 0.27)			
	C9D1	N	60	60	60	42	42	42
		Mean	66.0	71.9	6.0	69.0	68.3	-0.8
		SD	20.54	19.04	16.39	18.89	17.48	19.72
		Median	66.7	75.0	0.0	75.0	66.7	0.0
		95% CI	60.7, 71.3	67.0, 76.9	1.7, 10.2	63.2, 74.9	62.8, 73.7	-6.9, 5.4
		Q1, Q3	50.0, 83.3	58.3, 83.3	0.0, 16.7	58.3, 83.3	58.3, 83.3	-16.7, 16.7
		Min, Max	16.7, 100.0	25.0, 100.0	-33.3, 41.7	16.7, 100.0	16.7, 100.0	-33.3, 50.0
		Mean Diff (95% CI) [a]			6.0 (1.7, 10.2)			-0.8 (-6.9, 5.4)
		P-value [a]			0.006			0.796
		Mean Diff (95% CI) [b]			6.8 (-0.4, 13.9)			
		P-value [b]			0.062			
		Effect Size (95% CI) [c]			0.33 (0.12, 0.55)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	64.2	71.1	6.9	67.5	68.6	1.1
		SD	21.39	18.93	21.03	19.62	19.66	21.63
		Median	66.7	75.0	8.3	75.0	70.8	0.0
		95% CI	58.4, 70.0	66.0, 76.3	1.2, 12.7	60.2, 74.8	61.3, 76.0	-7.0, 9.2
		Q1, Q3	50.0, 83.3	66.7, 83.3	0.0, 16.7	50.0, 83.3	50.0, 83.3	-8.3, 16.7
		Min, Max	16.7, 100.0	16.7, 100.0	-83.3, 41.7	16.7, 100.0	16.7, 100.0	-41.7, 50.0
		Mean Diff (95% CI) [a]			6.9 (1.2, 12.7)			1.1 (-7.0, 9.2)
		P-value [a]			0.019			0.780
		Mean Diff (95% CI) [b]			5.8 (-3.8, 15.5)			
		P-value [b]			0.231			
		Effect Size (95% CI) [c]			0.29 (0.07, 0.50)			
	C11D1	N	45	45	45	23	23	23
		Mean	65.2	72.6	7.4	72.5	71.0	-1.4
		SD	21.34	17.01	19.64	17.84	14.84	17.34
		Median	66.7	75.0	8.3	83.3	66.7	0.0
		95% CI	58.8, 71.6	67.5, 77.7	1.5, 13.3	64.7, 80.2	64.6, 77.4	-8.9, 6.1
		Q1, Q3	50.0, 83.3	66.7, 83.3	0.0, 16.7	50.0, 83.3	58.3, 83.3	-16.7, 0.0
		Min, Max	16.7, 100.0	25.0, 100.0	-41.7, 50.0	41.7, 100.0	50.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			7.4 (1.5, 13.3)			-1.4 (-8.9, 6.1)
		P-value [a]			0.015			0.692
		Mean Diff (95% CI) [b]			8.9 (-0.8, 18.5)			
		P-value [b]			0.072			
		Effect Size (95% CI) [c]			0.43 (0.22, 0.65)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	66.5	71.1	4.7	71.1	71.9	0.9
		SD	21.93	18.36	17.58	16.52	17.39	18.61
		Median	66.7	66.7	0.0	75.0	66.7	0.0
		95% CI	59.5, 73.4	65.3, 76.9	-0.9, 10.2	63.1, 79.0	63.5, 80.3	-8.1, 9.8
		Q1, Q3	50.0, 83.3	66.7, 83.3	0.0, 16.7	58.3, 83.3	58.3, 83.3	-8.3, 16.7
		Min, Max	16.7, 100.0	33.3, 100.0	-25.0, 50.0	41.7, 100.0	41.7, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			4.7 (-0.9, 10.2)			0.9 (-8.1, 9.8)
		P-value [a]			0.096			0.840
		Mean Diff (95% CI) [b]			3.8 (-6.2, 13.7)			
		P-value [b]			0.448			
		Effect Size (95% CI) [c]			0.19 (-0.03, 0.40)			
	C13D1	N	33	33	33	15	15	15
		Mean	67.4	71.0	3.5	72.8	68.9	-3.9
		SD	21.08	16.15	17.93	17.67	15.26	14.73
		Median	66.7	66.7	0.0	75.0	66.7	0.0
		95% CI	60.0, 74.9	65.2, 76.7	-2.8, 9.9	63.0, 82.6	60.4, 77.3	-12.0, 4.3
		Q1, Q3	50.0, 83.3	58.3, 83.3	-8.3, 16.7	58.3, 83.3	58.3, 83.3	-16.7, 8.3
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 41.7	41.7, 100.0	50.0, 100.0	-25.0, 16.7
		Mean Diff (95% CI) [a]			3.5 (-2.8, 9.9)			-3.9 (-12.0, 4.3)
		P-value [a]			0.266			0.324
		Mean Diff (95% CI) [b]			7.4 (-3.2, 18.1)			
		P-value [b]			0.168			
		Effect Size (95% CI) [c]			0.36 (0.15, 0.58)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	66.9	71.7	4.8	70.8	69.4	-1.4
		SD	20.46	19.43	14.13	17.94	22.00	25.08
		Median	66.7	75.0	8.3	75.0	70.8	0.0
		95% CI	59.7, 74.2	64.8, 78.6	-0.2, 9.8	59.4, 82.2	55.5, 83.4	-17.3, 14.5
		Q1, Q3	50.0, 83.3	66.7, 83.3	-8.3, 16.7	54.2, 83.3	50.0, 83.3	-12.5, 16.7
		Min, Max	16.7, 100.0	16.7, 100.0	-16.7, 41.7	41.7, 100.0	33.3, 100.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			4.8 (-0.2, 9.8)			-1.4 (-17.3, 14.5)
		P-value [a]			0.060			0.851
		Mean Diff (95% CI) [b]			6.2 (-5.8, 18.1)			
		P-value [b]			0.303			
		Effect Size (95% CI) [c]			0.30 (0.09, 0.52)			
	C15D1	N	28	28	28	13	13	13
		Mean	64.9	67.0	2.1	70.5	67.3	-3.2
		SD	20.71	18.91	16.76	17.22	16.12	21.66
		Median	66.7	66.7	0.0	66.7	66.7	0.0
		95% CI	56.9, 72.9	59.6, 74.3	-4.4, 8.6	60.1, 80.9	57.6, 77.1	-16.3, 9.9
		Q1, Q3	50.0, 83.3	50.0, 83.3	-4.2, 8.3	58.3, 83.3	58.3, 75.0	-8.3, 8.3
		Min, Max	16.7, 100.0	16.7, 100.0	-33.3, 41.7	41.7, 100.0	41.7, 100.0	-41.7, 33.3
		Mean Diff (95% CI) [a]			2.1 (-4.4, 8.6)			-3.2 (-16.3, 9.9)
		P-value [a]			0.516			0.603
		Mean Diff (95% CI) [b]			5.3 (-7.2, 17.8)			
		P-value [b]			0.397			
		Effect Size (95% CI) [c]			0.26 (0.05, 0.47)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	66.7	69.0	2.4	68.3	63.3	-5.0
		SD	20.54	19.36	18.82	18.76	21.59	24.91
		Median	70.8	66.7	4.2	66.7	66.7	0.0
		95% CI	58.7, 74.6	61.5, 76.6	-4.9, 9.7	54.9, 81.8	47.9, 78.8	-22.8, 12.8
		Q1, Q3	50.0, 83.3	50.0, 83.3	-12.5, 16.7	50.0, 83.3	58.3, 66.7	-16.7, 8.3
		Min, Max	16.7, 100.0	33.3, 100.0	-50.0, 41.7	41.7, 100.0	25.0, 100.0	-58.3, 25.0
		Mean Diff (95% CI) [a]			2.4 (-4.9, 9.7)			-5.0 (-22.8, 12.8)
		P-value [a]			0.509			0.541
		Mean Diff (95% CI) [b]			7.4 (-7.9, 22.7)			
		P-value [b]			0.335			
		Effect Size (95% CI) [c]			0.36 (0.15, 0.58)			
	C17D1	N	26	26	26	7	7	7
		Mean	65.7	68.3	2.6	61.9	63.1	1.2
		SD	20.73	20.95	16.46	16.57	13.49	21.21
		Median	70.8	70.8	0.0	58.3	66.7	0.0
		95% CI	57.3, 74.1	59.8, 76.7	-4.1, 9.2	46.6, 77.2	50.6, 75.6	-18.4, 20.8
		Q1, Q3	50.0, 83.3	58.3, 83.3	-8.3, 16.7	50.0, 83.3	50.0, 66.7	0.0, 16.7
		Min, Max	16.7, 100.0	16.7, 100.0	-33.3, 41.7	41.7, 83.3	41.7, 83.3	-41.7, 25.0
		Mean Diff (95% CI) [a]			2.6 (-4.1, 9.2)			1.2 (-18.4, 20.8)
		P-value [a]			0.434			0.887
		Mean Diff (95% CI) [b]			1.4 (-13.8, 16.6)			
		P-value [b]			0.855			
		Effect Size (95% CI) [c]			0.07 (-0.15, 0.28)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	63.6	70.1	6.4	69.0	67.9	-1.2
		SD	21.75	19.19	18.35	20.81	18.28	16.27
		Median	66.7	66.7	0.0	66.7	66.7	0.0
		95% CI	54.0, 73.3	61.6, 78.6	-1.7, 14.6	49.8, 88.3	51.0, 84.8	-16.2, 13.9
		Q1, Q3	50.0, 83.3	66.7, 83.3	0.0, 16.7	50.0, 83.3	50.0, 83.3	-16.7, 8.3
		Min, Max	16.7, 100.0	16.7, 100.0	-33.3, 41.7	41.7, 100.0	50.0, 100.0	-25.0, 25.0
		Mean Diff (95% CI) [a]			6.4 (-1.7, 14.6)			-1.2 (-16.2, 13.9)
		P-value [a]			0.115			0.853
		Mean Diff (95% CI) [b]			7.6 (-8.3, 23.6)			
		P-value [b]			0.335			
		Effect Size (95% CI) [c]			0.37 (0.16, 0.59)			
	C19D1	N	20	20	20	6	6	6
		Mean	64.6	68.8	4.2	66.7	63.9	-2.8
		SD	22.27	20.75	14.93	21.73	12.55	17.21
		Median	70.8	66.7	0.0	62.5	66.7	-8.3
		95% CI	54.2, 75.0	59.0, 78.5	-2.8, 11.2	43.9, 89.5	50.7, 77.1	-20.8, 15.3
		Q1, Q3	50.0, 83.3	66.7, 83.3	0.0, 8.3	50.0, 83.3	50.0, 66.7	-16.7, 8.3
		Min, Max	16.7, 100.0	16.7, 100.0	-33.3, 33.3	41.7, 100.0	50.0, 83.3	-16.7, 25.0
		Mean Diff (95% CI) [a]			4.2 (-2.8, 11.2)			-2.8 (-20.8, 15.3)
		P-value [a]			0.227			0.709
		Mean Diff (95% CI) [b]			6.9 (-7.9, 21.8)			
		P-value [b]			0.343			
		Effect Size (95% CI) [c]			0.34 (0.13, 0.55)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	19	19	19	4	4	4
		Mean	68.0	69.7	1.8	64.6	66.7	2.1
		SD	21.56	17.83	13.20	14.23	13.61	4.17
		Median	75.0	66.7	0.0	62.5	66.7	0.0
		95% CI	57.6, 78.4	61.1, 78.3	-4.6, 8.1	41.9, 87.2	45.0, 88.3	-4.5, 8.7
		Q1, Q3	50.0, 83.3	66.7, 83.3	-8.3, 8.3	54.2, 75.0	58.3, 75.0	0.0, 4.2
		Min, Max	16.7, 100.0	16.7, 100.0	-16.7, 33.3	50.0, 83.3	50.0, 83.3	0.0, 8.3
		Mean Diff (95% CI) [a]			1.8 (-4.6, 8.1)			2.1 (-4.5, 8.7)
		P-value [a]			0.570			0.391
		Mean Diff (95% CI) [b]			-0.3 (-14.4, 13.8)			
		P-value [b]			0.962			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.20)			
	C21D1	N	18	18	18	4	4	4
		Mean	67.1	71.8	4.6	64.6	62.5	-2.1
		SD	21.86	16.20	15.71	14.23	15.96	10.49
		Median	75.0	66.7	8.3	62.5	58.3	0.0
		95% CI	56.3, 78.0	63.7, 79.8	-3.2, 12.4	41.9, 87.2	37.1, 87.9	-18.8, 14.6
		Q1, Q3	50.0, 83.3	66.7, 83.3	-8.3, 16.7	54.2, 75.0	50.0, 75.0	-8.3, 4.2
		Min, Max	16.7, 100.0	33.3, 100.0	-16.7, 33.3	50.0, 83.3	50.0, 83.3	-16.7, 8.3
		Mean Diff (95% CI) [a]			4.6 (-3.2, 12.4)			-2.1 (-18.8, 14.6)
		P-value [a]			0.228			0.718
		Mean Diff (95% CI) [b]			6.7 (-10.6, 24.1)			
		P-value [b]			0.429			
		Effect Size (95% CI) [c]			0.33 (0.12, 0.54)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	69.4	71.7	2.2	63.9	72.2	8.3
		SD	21.28	16.00	13.90	17.35	25.46	8.33
		Median	75.0	66.7	0.0	58.3	66.7	8.3
		95% CI	57.7, 81.2	62.8, 80.5	-5.5, 9.9	20.8, 107.0	9.0, 135.5	-12.4, 29.0
		Q1, Q3	58.3, 83.3	66.7, 83.3	-8.3, 8.3	50.0, 83.3	50.0, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	41.7, 91.7	-33.3, 25.0	50.0, 83.3	50.0, 100.0	0.0, 16.7
		Mean Diff (95% CI) [a]			2.2 (-5.5, 9.9)			8.3 (-12.4, 29.0)
		P-value [a]			0.546			0.225
		Mean Diff (95% CI) [b]			-6.1 (-24.0, 11.8)			
		P-value [b]			0.479			
		Effect Size (95% CI) [c]			-0.30 (-0.51, -0.09)			
	C23D1	N	11	11	11	3	3	3
		Mean	66.7	68.9	2.3	63.9	69.4	5.6
		SD	23.57	19.40	11.24	17.35	12.73	4.81
		Median	75.0	75.0	0.0	58.3	66.7	8.3
		95% CI	50.8, 82.5	55.9, 82.0	-5.3, 9.8	20.8, 107.0	37.8, 101.1	-6.4, 17.5
		Q1, Q3	50.0, 83.3	50.0, 83.3	0.0, 8.3	50.0, 83.3	58.3, 83.3	0.0, 8.3
		Min, Max	16.7, 100.0	33.3, 100.0	-16.7, 16.7	50.0, 83.3	58.3, 83.3	0.0, 8.3
		Mean Diff (95% CI) [a]			2.3 (-5.3, 9.8)			5.6 (-6.4, 17.5)
		P-value [a]			0.518			0.184
		Mean Diff (95% CI) [b]			-3.3 (-18.1, 11.5)			
		P-value [b]			0.638			
		Effect Size (95% CI) [c]			-0.16 (-0.37, 0.05)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	67.5	70.0	2.5	66.7	66.7	0.0
		SD	21.32	20.11	11.82	23.57	23.57	0.00
		Median	75.0	75.0	4.2	66.7	66.7	0.0
		95% CI	52.2, 82.8	55.6, 84.4	-6.0, 11.0	-145.1, 278.4	-145.1, 278.4	0.0, 0.0
		Q1, Q3	58.3, 83.3	58.3, 83.3	0.0, 8.3	50.0, 83.3	50.0, 83.3	0.0, 0.0
		Min, Max	16.7, 83.3	33.3, 100.0	-16.7, 16.7	50.0, 83.3	50.0, 83.3	0.0, 0.0
		Mean Diff (95% CI) [a]			2.5 (-6.0, 11.0)			0.0 (0.0, 0.0)
		P-value [a]			0.520			NE
		Mean Diff (95% CI) [b]			2.5 (-16.8, 21.8)			
		P-value [b]			0.779			
		Effect Size (95% CI) [c]			0.12 (-0.09, 0.34)			
	C25D1	N	9	9	9	0	0	0
		Mean	65.7	68.5	2.8	NE	NE	NE
		SD	21.83	23.85	9.32	NE	NE	NE
		Median	75.0	66.7	0.0	NE	NE	NE
		95% CI	49.0, 82.5	50.2, 86.9	-4.4, 9.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	58.3, 83.3	58.3, 83.3	0.0, 8.3	NE, NE	NE, NE	NE, NE
		Min, Max	16.7, 83.3	16.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			2.8 (-4.4, 9.9)			NE (NE, NE)
		P-value [a]			0.397			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	75.0	70.8	-4.2	83.3	100.0	16.7
		SD	11.79	22.71	20.89	NE	NE	NE
		Median	79.2	83.3	0.0	83.3	100.0	16.7
		95% CI	65.1, 84.9	51.8, 89.8	-21.6, 13.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.8, 83.3	58.3, 83.3	-8.3, 8.3	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	50.0, 83.3	25.0, 91.7	-50.0, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			-4.2 (-21.6, 13.3)			16.7 (NE, NE)
		P-value [a]			0.590			NE
		Mean Diff (95% CI) [b]			-20.8 (-73.2, 31.6)			
		P-value [b]			0.378			
		Effect Size (95% CI) [c]			-1.02 (-1.25, -0.80)			
	C27D1	N	8	8	8	1	1	1
		Mean	75.0	80.2	5.2	83.3	100.0	16.7
		SD	11.79	14.73	10.85	NE	NE	NE
		Median	79.2	83.3	8.3	83.3	100.0	16.7
		95% CI	65.1, 84.9	67.9, 92.5	-3.9, 14.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.8, 83.3	70.8, 87.5	0.0, 12.5	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	50.0, 83.3	58.3, 100.0	-16.7, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			5.2 (-3.9, 14.3)			16.7 (NE, NE)
		P-value [a]			0.217			NE
		Mean Diff (95% CI) [b]			-11.5 (-38.7, 15.8)			
		P-value [b]			0.353			
		Effect Size (95% CI) [c]			-0.56 (-0.78, -0.35)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	73.8	72.6	-1.2	83.3	100.0	16.7
		SD	12.20	11.50	8.91	NE	NE	NE
		Median	75.0	75.0	0.0	83.3	100.0	16.7
		95% CI	62.5, 85.1	62.0, 83.3	-9.4, 7.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 83.3	58.3, 83.3	-8.3, 8.3	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	50.0, 83.3	58.3, 83.3	-16.7, 8.3	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			-1.2 (-9.4, 7.0)			16.7 (NE, NE)
		P-value [a]			0.736			NE
		Mean Diff (95% CI) [b]			-17.9 (-41.2, 5.4)			
		P-value [b]			0.110			
		Effect Size (95% CI) [c]			-0.88 (-1.10, -0.65)			
	C29D1	N	4	4	4	1	1	1
		Mean	68.8	64.6	-4.2	83.3	50.0	-33.3
		SD	14.23	14.23	14.43	NE	NE	NE
		Median	70.8	62.5	0.0	83.3	50.0	-33.3
		95% CI	46.1, 91.4	41.9, 87.2	-27.1, 18.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	58.3, 79.2	54.2, 75.0	-12.5, 4.2	83.3, 83.3	50.0, 50.0	-33.3, -33.3
		Min, Max	50.0, 83.3	50.0, 83.3	-25.0, 8.3	83.3, 83.3	50.0, 50.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			-4.2 (-27.1, 18.8)			-33.3 (NE, NE)
		P-value [a]			0.604			NE
		Mean Diff (95% CI) [b]			29.2 (-22.2, 80.5)			
		P-value [b]			0.168			
		Effect Size (95% CI) [c]			1.43 (1.19, 1.67)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	72.9	72.9	0.0	83.3	33.3	-50.0
		SD	15.77	12.50	6.80	NE	NE	NE
		Median	79.2	75.0	0.0	83.3	33.3	-50.0
		95% CI	47.8, 98.0	53.0, 92.8	-10.8, 10.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	62.5, 83.3	62.5, 83.3	-4.2, 4.2	83.3, 83.3	33.3, 33.3	-50.0, -50.0
		Min, Max	50.0, 83.3	58.3, 83.3	-8.3, 8.3	83.3, 83.3	33.3, 33.3	-50.0, -50.0
		Mean Diff (95% CI) [a]			0.0 (-10.8, 10.8)			-50.0 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			50.0 (25.8, 74.2)			
		P-value [b]			0.007			
		Effect Size (95% CI) [c]			2.45 (2.17, 2.74)			
	C31D1	N	2	2	2	1	1	1
		Mean	66.7	70.8	4.2	83.3	66.7	-16.7
		SD	23.57	29.46	5.89	NE	NE	NE
		Median	66.7	70.8	4.2	83.3	66.7	-16.7
		95% CI	-145.1, 278.4	-193.9, 335.5	-48.8, 57.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	50.0, 83.3	50.0, 91.7	0.0, 8.3	83.3, 83.3	66.7, 66.7	-16.7, -16.7
		Min, Max	50.0, 83.3	50.0, 91.7	0.0, 8.3	83.3, 83.3	66.7, 66.7	-16.7, -16.7
		Mean Diff (95% CI) [a]			4.2 (-48.8, 57.1)			-16.7 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			20.8 (-70.9, 112.5)			
		P-value [b]			0.212			
		Effect Size (95% CI) [c]			1.02 (0.80, 1.25)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	66.7	75.0	8.3	83.3	83.3	0.0
		SD	23.57	11.79	11.79	NE	NE	NE
		Median	66.7	75.0	8.3	83.3	83.3	0.0
		95% CI	-145.1, 278.4	-30.9, 180.9	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	50.0, 83.3	66.7, 83.3	0.0, 16.7	83.3, 83.3	83.3, 83.3	0.0, 0.0
		Min, Max	50.0, 83.3	66.7, 83.3	0.0, 16.7	83.3, 83.3	83.3, 83.3	0.0, 0.0
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			0.0 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			8.3 (-175.1, 191.7)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			0.41 (0.19, 0.62)			
	C33D1	N	3	3	3	1	1	1
		Mean	72.2	69.4	-2.8	83.3	66.7	-16.7
		SD	19.25	17.35	4.81	NE	NE	NE
		Median	83.3	75.0	0.0	83.3	66.7	-16.7
		95% CI	24.4, 120.0	26.4, 112.5	-14.7, 9.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	50.0, 83.3	50.0, 83.3	-8.3, 0.0	83.3, 83.3	66.7, 66.7	-16.7, -16.7
		Min, Max	50.0, 83.3	50.0, 83.3	-8.3, 0.0	83.3, 83.3	66.7, 66.7	-16.7, -16.7
		Mean Diff (95% CI) [a]			-2.8 (-14.7, 9.2)			-16.7 (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			13.9 (-10.0, 37.8)			
		P-value [b]			0.130			
		Effect Size (95% CI) [c]			0.68 (0.46, 0.90)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	72.2	80.6	8.3	NE	NE	NE
		SD	19.25	26.79	8.33	NE	NE	NE
		Median	83.3	91.7	8.3	NE	NE	NE
		95% CI	24.4, 120.0	14.0, 147.1	-12.4, 29.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	50.0, 83.3	50.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	50.0, 83.3	50.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-12.4, 29.0)			NE (NE, NE)
		P-value [a]			0.225			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	66.7	66.7	0.0	NE	NE	NE
		SD	23.57	35.36	11.79	NE	NE	NE
		Median	66.7	66.7	0.0	NE	NE	NE
		95% CI	-145.1, 278.4	-251.0, 384.3	-105.9, 105.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	50.0, 83.3	41.7, 91.7	-8.3, 8.3	NE, NE	NE, NE	NE, NE
		Min, Max	50.0, 83.3	41.7, 91.7	-8.3, 8.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (-105.9, 105.9)			NE (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	72.2	75.0	2.8	NE	NE	NE
		SD	19.25	30.05	12.73	NE	NE	NE
		Median	83.3	83.3	0.0	NE	NE	NE
		95% CI	24.4, 120.0	0.4, 149.6	-28.8, 34.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	50.0, 83.3	41.7, 100.0	-8.3, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	50.0, 83.3	41.7, 100.0	-8.3, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			2.8 (-28.8, 34.4)			NE (NE, NE)
		P-value [a]			0.742			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	72.2	75.0	2.8	NE	NE	NE
		SD	19.25	22.05	4.81	NE	NE	NE
		Median	83.3	83.3	0.0	NE	NE	NE
		95% CI	24.4, 120.0	20.2, 129.8	-9.2, 14.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	50.0, 83.3	50.0, 91.7	0.0, 8.3	NE, NE	NE, NE	NE, NE
		Min, Max	50.0, 83.3	50.0, 91.7	0.0, 8.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			2.8 (-9.2, 14.7)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	83.3	83.3	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	83.3	83.3	0.0	NE	NE	NE
		95% CI	83.3, 83.3	83.3, 83.3	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	83.3, 83.3	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	83.3, 83.3	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	83.3	91.7	8.3	NE	NE	NE
		SD	0.00	11.79	11.79	NE	NE	NE
		Median	83.3	91.7	8.3	NE	NE	NE
		95% CI	83.3, 83.3	-14.2, 197.6	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	83.3, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	83.3, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	83.3	87.5	4.2	NE	NE	NE
		SD	0.00	5.89	5.89	NE	NE	NE
		Median	83.3	87.5	4.2	NE	NE	NE
		95% CI	83.3, 83.3	34.6, 140.4	-48.8, 57.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	83.3, 91.7	0.0, 8.3	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	83.3, 91.7	0.0, 8.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			4.2 (-48.8, 57.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	83.3	79.2	-4.2	NE	NE	NE
		SD	0.00	5.89	5.89	NE	NE	NE
		Median	83.3	79.2	-4.2	NE	NE	NE
		95% CI	83.3, 83.3	26.2, 132.1	-57.1, 48.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	75.0, 83.3	-8.3, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	75.0, 83.3	-8.3, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-4.2 (-57.1, 48.8)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	83.3	83.3	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	83.3	83.3	0.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	83.3, 83.3	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	83.3, 83.3	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	83.3	91.7	8.3	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	83.3	91.7	8.3	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	91.7, 91.7	8.3, 8.3	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	91.7, 91.7	8.3, 8.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	130	130	130	125	125	125
		Mean	64.1	57.9	-6.2	64.3	56.0	-8.3
		SD	21.13	25.57	24.10	19.82	21.39	24.05
		Median	66.7	66.7	0.0	66.7	58.3	-8.3
		95% CI	60.4, 67.8	53.4, 62.3	-10.4, -2.0	60.8, 67.8	52.2, 59.8	-12.5, -4.0
		Q1, Q3	50.0, 83.3	41.7, 83.3	-16.7, 8.3	50.0, 83.3	41.7, 66.7	-25.0, 8.3
		Min, Max	8.3, 100.0	0.0, 100.0	-83.3, 50.0	8.3, 100.0	0.0, 100.0	-83.3, 50.0
		Mean Diff (95% CI) [a]			-6.2 (-10.4, -2.0)			-8.3 (-12.5, -4.0)
		P-value [a]			0.004			<.001
		Mean Diff (95% CI) [b]			2.0 (-3.9, 8.0)			
		P-value [b]			0.498			
		Effect Size (95% CI) [c]			0.10 (-0.11, 0.31)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	69.6	69.6	0.0	63.0	43.5	-19.4
		SD	15.54	15.54	11.79	20.03	29.10	42.29
		Median	66.7	70.8	0.0	66.7	41.7	-8.3
		95% CI	60.7, 78.6	60.7, 78.6	-6.8, 6.8	47.6, 78.4	21.1, 65.9	-51.9, 13.1
		Q1, Q3	58.3, 83.3	58.3, 83.3	-8.3, 8.3	50.0, 75.0	33.3, 66.7	-16.7, -8.3
		Min, Max	50.0, 100.0	41.7, 91.7	-25.0, 16.7	33.3, 100.0	0.0, 83.3	-100.0, 50.0
		Mean Diff (95% CI) [a]			0.0 (-6.8, 6.8)			-19.4 (-51.9, 13.1)
		P-value [a]			1.000			0.205
		Mean Diff (95% CI) [b]			19.4 (-5.2, 44.1)			
		P-value [b]			0.115			
		Effect Size (95% CI) [c]			0.95 (0.73, 1.18)			
Physical Functioning	Baseline	N	174			165		
		Mean	78.4			78.2		
		SD	19.90			19.73		
		Median	86.7			86.7		
		95% CI	75.4, 81.4			75.1, 81.2		
		Q1, Q3	66.7, 93.3			66.7, 93.3		
		Min, Max	20.0, 100.0			6.7, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	78.7	76.6	-2.2	79.4	75.3	-4.1
		SD	20.12	21.87	14.77	19.42	21.20	12.26
		95% CI	75.5, 81.9	73.1, 80.1	-4.5, 0.2	76.2, 82.6	71.8, 78.8	-6.1, -2.0
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	66.7, 93.3	60.0, 93.3	-6.7, 6.7	66.7, 93.3	60.0, 93.3	-6.7, 0.0
		Min, Max	20.0, 100.0	6.7, 100.0	-60.0, 31.7	6.7, 100.0	13.3, 100.0	-46.7, 33.3
		Mean Diff (95% CI) [a]			-2.2 (-4.5, 0.2)			-4.1 (-6.1, -2.0)
		P-value [a]			0.073			<.001
		Mean Diff (95% CI) [b]			1.9 (-1.2, 5.0)			
		P-value [b]			0.235			
		Effect Size (95% CI) [c]			0.09 (-0.12, 0.31)			
	C3D1	N	124	124	124	102	102	102
		Mean	80.3	79.3	-1.1	80.3	78.4	-1.9
		SD	17.83	20.56	14.39	17.21	18.54	12.96
		95% CI	77.2, 83.5	75.6, 82.9	-3.6, 1.5	76.9, 83.7	74.7, 82.0	-4.5, 0.6
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	70.0, 93.3	66.7, 100.0	-6.7, 6.7	66.7, 93.3	66.7, 93.3	-6.7, 0.0
		Min, Max	26.7, 100.0	20.0, 100.0	-46.7, 41.7	33.3, 100.0	33.3, 100.0	-46.7, 40.0
		Mean Diff (95% CI) [a]			-1.1 (-3.6, 1.5)			-1.9 (-4.5, 0.6)
		P-value [a]			0.403			0.139
		Mean Diff (95% CI) [b]			0.8 (-2.8, 4.5)			
		P-value [b]			0.653			
		Effect Size (95% CI) [c]			0.04 (-0.17, 0.25)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	79.0	79.5	0.5	80.6	77.0	-3.6
		SD	19.12	21.47	14.97	17.06	19.16	14.77
		95% CI	75.4, 82.6	75.5, 83.5	-2.3, 3.3	77.1, 84.1	73.0, 80.9	-6.6, -0.6
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	66.7, 93.3	70.0, 93.3	-6.7, 6.7	66.7, 93.3	60.0, 93.3	-13.3, 0.0
		Min, Max	26.7, 100.0	6.7, 100.0	-46.7, 33.3	33.3, 100.0	33.3, 100.0	-40.0, 40.0
		Mean Diff (95% CI) [a]			0.5 (-2.3, 3.3)			-3.6 (-6.6, -0.6)
		P-value [a]			0.719			0.020
		Mean Diff (95% CI) [b]			4.1 (0.0, 8.2)			
		P-value [b]			0.049			
		Effect Size (95% CI) [c]			0.21 (-0.01, 0.42)			
	C5D1	N	97	97	97	80	80	80
		Mean	79.7	79.0	-0.7	80.9	77.3	-3.7
		SD	18.77	20.28	13.72	17.05	19.31	13.53
		95% CI	75.9, 83.5	75.0, 83.1	-3.4, 2.1	77.1, 84.7	73.0, 81.6	-6.7, -0.7
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	66.7, 93.3	73.3, 93.3	-6.7, 6.7	70.0, 93.3	60.0, 93.3	-13.3, 0.0
		Min, Max	26.7, 100.0	13.3, 100.0	-40.0, 40.0	33.3, 100.0	20.0, 100.0	-40.0, 33.3
		Mean Diff (95% CI) [a]			-0.7 (-3.4, 2.1)			-3.7 (-6.7, -0.7)
		P-value [a]			0.634			0.018
		Mean Diff (95% CI) [b]			3.0 (-1.1, 7.1)			
		P-value [b]			0.147			
		Effect Size (95% CI) [c]			0.15 (-0.06, 0.36)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	69	69	69
		Mean	80.8	83.6	2.9	81.0	77.6	-3.4
		SD	18.75	18.38	11.84	15.93	18.79	13.33
		95% CI	77.0, 84.6	79.9, 87.4	0.5, 5.3	77.2, 84.8	73.1, 82.1	-6.6, -0.2
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	73.3, 93.3	74.2, 100.0	0.0, 6.7	66.7, 93.3	60.0, 93.3	-6.7, 6.7
		Min, Max	26.7, 100.0	13.3, 100.0	-33.3, 33.3	33.3, 100.0	26.7, 100.0	-46.7, 20.0
		Mean Diff (95% CI) [a]			2.9 (0.5, 5.3)			-3.4 (-6.6, -0.2)
		P-value [a]			0.020			0.038
		Mean Diff (95% CI) [b]			6.3 (2.4, 10.2)			
		P-value [b]			0.002			
		Effect Size (95% CI) [c]			0.32 (0.10, 0.53)			
	C7D1	N	78	78	78	53	53	53
		Mean	80.5	83.2	2.6	80.9	78.7	-2.2
		SD	18.29	18.85	12.47	16.99	17.20	13.43
		95% CI	76.4, 84.7	78.9, 87.4	-0.2, 5.4	76.2, 85.6	74.0, 83.5	-5.9, 1.5
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	73.3, 93.3	80.0, 93.3	-6.7, 6.7	66.7, 93.3	66.7, 93.3	-13.3, 6.7
		Min, Max	26.7, 100.0	20.0, 100.0	-40.0, 40.0	33.3, 100.0	33.3, 100.0	-26.7, 33.3
		Mean Diff (95% CI) [a]			2.6 (-0.2, 5.4)			-2.2 (-5.9, 1.5)
		P-value [a]			0.068			0.245
		Mean Diff (95% CI) [b]			4.8 (0.3, 9.3)			
		P-value [b]			0.039			
		Effect Size (95% CI) [c]			0.24 (0.03, 0.45)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	80.2	81.4	1.2	81.3	78.8	-2.5
		SD	18.60	20.32	13.68	17.14	17.39	12.98
		95% CI	76.0, 84.5	76.8, 86.0	-1.9, 4.3	76.5, 86.2	73.9, 83.7	-6.2, 1.2
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	66.7, 93.3	73.3, 100.0	-6.7, 6.7	66.7, 93.3	66.7, 93.3	-6.7, 6.7
		Min, Max	26.7, 100.0	13.3, 100.0	-46.7, 35.6	33.3, 100.0	33.3, 100.0	-33.3, 26.7
		Mean Diff (95% CI) [a]			1.2 (-1.9, 4.3)			-2.5 (-6.2, 1.2)
		P-value [a]			0.450			0.174
		Mean Diff (95% CI) [b]			3.7 (-1.1, 8.6)			
		P-value [b]			0.130			
		Effect Size (95% CI) [c]			0.19 (-0.03, 0.40)			
	C9D1	N	60	60	60	42	42	42
		Mean	80.4	81.9	1.5	80.8	77.9	-2.9
		SD	18.79	19.18	15.09	17.60	17.14	12.41
		95% CI	75.5, 85.2	76.9, 86.8	-2.4, 5.4	75.3, 86.3	72.6, 83.3	-6.8, 1.0
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	66.7, 96.7	66.7, 100.0	-6.7, 6.7	66.7, 93.3	66.7, 93.3	-13.3, 6.7
		Min, Max	33.3, 100.0	26.7, 100.0	-40.0, 42.2	33.3, 100.0	40.0, 100.0	-26.7, 26.7
		Mean Diff (95% CI) [a]			1.5 (-2.4, 5.4)			-2.9 (-6.8, 1.0)
		P-value [a]			0.441			0.138
		Mean Diff (95% CI) [b]			4.4 (-1.2, 10.0)			
		P-value [b]			0.122			
		Effect Size (95% CI) [c]			0.22 (0.01, 0.43)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	80.1	80.9	0.8	78.9	77.3	-1.6
		SD	19.55	20.19	16.26	17.95	17.21	11.44
		95% CI	74.7, 85.4	75.4, 86.4	-3.6, 5.3	72.2, 85.6	70.9, 83.8	-5.8, 2.7
		Median	86.7	86.7	0.0	86.7	80.0	0.0
		Q1, Q3	66.7, 100.0	73.3, 100.0	-6.7, 6.7	66.7, 93.3	60.0, 93.3	-13.3, 6.7
		Min, Max	33.3, 100.0	20.0, 100.0	-60.0, 42.2	33.3, 100.0	40.0, 100.0	-20.0, 26.7
		Mean Diff (95% CI) [a]			0.8 (-3.6, 5.3)			-1.6 (-5.8, 2.7)
		P-value [a]			0.715			0.462
		Mean Diff (95% CI) [b]			2.4 (-4.3, 9.0)			
		P-value [b]			0.482			
		Effect Size (95% CI) [c]			0.12 (-0.09, 0.33)			
	C11D1	N	46	46	46	23	23	23
		Mean	80.3	81.4	1.2	85.8	82.3	-3.5
		SD	18.74	21.77	19.69	13.97	12.97	12.85
		95% CI	74.7, 85.8	75.0, 87.9	-4.7, 7.0	79.8, 91.8	76.7, 87.9	-9.0, 2.1
		Median	86.7	86.7	0.0	93.3	86.7	-6.7
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 13.3	80.0, 93.3	73.3, 93.3	-13.3, 6.7
		Min, Max	40.0, 100.0	26.7, 100.0	-66.7, 60.0	46.7, 100.0	60.0, 100.0	-26.7, 26.7
		Mean Diff (95% CI) [a]			1.2 (-4.7, 7.0)			-3.5 (-9.0, 2.1)
		P-value [a]			0.682			0.208
		Mean Diff (95% CI) [b]			4.7 (-4.4, 13.7)			
		P-value [b]			0.306			
		Effect Size (95% CI) [c]			0.24 (0.02, 0.45)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	80.3	82.0	1.7	84.2	82.5	-1.8
		SD	19.42	21.20	16.36	13.74	14.44	14.03
		95% CI	74.2, 86.4	75.3, 88.6	-3.5, 6.8	77.6, 90.8	75.5, 89.4	-8.5, 5.0
		Median	86.7	86.7	0.0	86.7	86.7	0.0
		Q1, Q3	66.7, 100.0	73.3, 100.0	-6.7, 6.7	80.0, 93.3	73.3, 93.3	-6.7, 6.7
		Min, Max	40.0, 100.0	13.3, 100.0	-53.3, 60.0	46.7, 100.0	53.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			1.7 (-3.5, 6.8)			-1.8 (-8.5, 5.0)
		P-value [a]			0.518			0.592
		Mean Diff (95% CI) [b]			3.4 (-5.3, 12.1)			
		P-value [b]			0.435			
		Effect Size (95% CI) [c]			0.17 (-0.04, 0.39)			
	C13D1	N	32	32	32	15	15	15
		Mean	79.5	84.0	4.4	81.3	80.0	-1.3
		SD	19.80	17.50	16.11	15.57	16.33	17.85
		95% CI	72.4, 86.7	77.6, 90.3	-1.4, 10.2	72.7, 90.0	71.0, 89.0	-11.2, 8.6
		Median	86.7	86.7	0.0	80.0	80.0	0.0
		Q1, Q3	66.7, 100.0	80.0, 100.0	-6.7, 13.3	66.7, 93.3	73.3, 93.3	-6.7, 6.7
		Min, Max	40.0, 100.0	33.3, 100.0	-20.0, 60.0	46.7, 100.0	33.3, 100.0	-46.7, 33.3
		Mean Diff (95% CI) [a]			4.4 (-1.4, 10.2)			-1.3 (-11.2, 8.6)
		P-value [a]			0.130			0.777
		Mean Diff (95% CI) [b]			5.8 (-4.7, 16.3)			
		P-value [b]			0.275			
		Effect Size (95% CI) [c]			0.29 (0.08, 0.50)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	79.3	81.8	2.5	80.0	80.0	0.0
		SD	19.30	19.10	11.96	16.58	16.58	15.04
		95% CI	72.5, 86.2	75.0, 88.6	-1.8, 6.7	69.5, 90.5	69.5, 90.5	-9.6, 9.6
		Median	86.7	86.7	0.0	83.3	80.0	0.0
		Q1, Q3	66.7, 93.3	66.7, 100.0	0.0, 6.7	66.7, 93.3	66.7, 93.3	0.0, 3.3
		Min, Max	40.0, 100.0	33.3, 100.0	-26.7, 33.3	46.7, 100.0	46.7, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			2.5 (-1.8, 6.7)			0.0 (-9.6, 9.6)
		P-value [a]			0.243			1.000
		Mean Diff (95% CI) [b]			2.5 (-6.2, 11.2)			
		P-value [b]			0.570			
		Effect Size (95% CI) [c]			0.12 (-0.09, 0.34)			
	C15D1	N	28	28	28	13	13	13
		Mean	79.7	81.0	1.2	80.0	79.5	-0.5
		SD	18.61	17.94	15.90	15.87	12.01	15.02
		95% CI	72.5, 86.9	74.0, 87.9	-4.9, 7.4	70.4, 89.6	72.2, 86.7	-9.6, 8.6
		Median	86.7	86.7	0.0	80.0	80.0	0.0
		Q1, Q3	66.7, 93.3	66.7, 100.0	-6.7, 13.3	66.7, 93.3	73.3, 86.7	-6.7, 0.0
		Min, Max	40.0, 100.0	33.3, 100.0	-40.0, 33.3	46.7, 100.0	60.0, 100.0	-20.0, 40.0
		Mean Diff (95% CI) [a]			1.2 (-4.9, 7.4)			-0.5 (-9.6, 8.6)
		P-value [a]			0.681			0.904
		Mean Diff (95% CI) [b]			1.8 (-8.9, 12.4)			
		P-value [b]			0.739			
		Effect Size (95% CI) [c]			0.09 (-0.12, 0.30)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

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[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	78.8	79.8	1.0	76.7	80.7	4.0
		SD	19.63	23.06	16.70	16.70	11.09	9.00
		95% CI	71.2, 86.4	70.8, 88.7	-5.5, 7.4	64.7, 88.6	72.7, 88.6	-2.4, 10.4
		Median	86.7	86.7	0.0	80.0	76.7	0.0
		Q1, Q3	66.7, 93.3	63.3, 100.0	-3.3, 10.0	66.7, 93.3	73.3, 93.3	0.0, 6.7
		Min, Max	40.0, 100.0	20.0, 100.0	-46.7, 33.3	46.7, 100.0	66.7, 100.0	-6.7, 26.7
		Mean Diff (95% CI) [a]			1.0 (-5.5, 7.4)			4.0 (-2.4, 10.4)
		P-value [a]			0.765			0.193
		Mean Diff (95% CI) [b]			-3.0 (-14.4, 8.3)			
		P-value [b]			0.588			
		Effect Size (95% CI) [c]			-0.15 (-0.37, 0.06)			
	C17D1	N	26	26	26	7	7	7
		Mean	79.7	81.5	1.8	70.5	78.1	7.6
		SD	18.62	20.25	12.59	15.33	12.00	13.57
		95% CI	72.2, 87.3	73.4, 89.7	-3.3, 6.9	56.3, 84.7	67.0, 89.2	-4.9, 20.2
		Median	86.7	86.7	0.0	66.7	73.3	6.7
		Q1, Q3	66.7, 93.3	66.7, 100.0	-6.7, 6.7	60.0, 80.0	66.7, 86.7	6.7, 6.7
		Min, Max	40.0, 100.0	20.0, 100.0	-20.0, 33.3	46.7, 93.3	66.7, 100.0	-13.3, 33.3
		Mean Diff (95% CI) [a]			1.8 (-3.3, 6.9)			7.6 (-4.9, 20.2)
		P-value [a]			0.474			0.188
		Mean Diff (95% CI) [b]			-5.8 (-16.9, 5.3)			
		P-value [b]			0.293			
		Effect Size (95% CI) [c]			-0.29 (-0.51, -0.08)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	77.6	78.2	0.6	77.1	79.0	1.9
		SD	19.36	25.13	14.68	13.25	14.62	9.97
		95% CI	69.0, 86.2	67.0, 89.3	-5.9, 7.1	64.9, 89.4	65.5, 92.6	-7.3, 11.1
		Median	80.0	80.0	0.0	80.0	73.3	6.7
		Q1, Q3	66.7, 93.3	73.3, 100.0	-6.7, 13.3	66.7, 93.3	66.7, 93.3	0.0, 6.7
		Min, Max	40.0, 100.0	20.0, 100.0	-26.7, 33.3	60.0, 93.3	60.0, 100.0	-20.0, 6.7
		Mean Diff (95% CI) [a]			0.6 (-5.9, 7.1)			1.9 (-7.3, 11.1)
		P-value [a]			0.848			0.631
		Mean Diff (95% CI) [b]			-1.3 (-13.6, 11.0)			
		P-value [b]			0.830			
		Effect Size (95% CI) [c]			-0.07 (-0.28, 0.15)			
	C19D1	N	20	20	20	6	6	6
		Mean	78.3	78.0	-0.3	78.9	71.1	-7.8
		SD	20.16	23.60	10.70	13.61	14.40	17.60
		95% CI	68.9, 87.8	67.0, 89.0	-5.3, 4.7	64.6, 93.2	56.0, 86.2	-26.2, 10.7
		Median	83.3	86.7	0.0	80.0	70.0	0.0
		Q1, Q3	63.3, 96.7	66.7, 96.7	-3.3, 3.3	66.7, 93.3	60.0, 80.0	-26.7, 6.7
		Min, Max	40.0, 100.0	20.0, 100.0	-20.0, 20.0	60.0, 93.3	53.3, 93.3	-33.3, 6.7
		Mean Diff (95% CI) [a]			-0.3 (-5.3, 4.7)			-7.8 (-26.2, 10.7)
		P-value [a]			0.891			0.328
		Mean Diff (95% CI) [b]			7.4 (-4.5, 19.4)			
		P-value [b]			0.211			
		Effect Size (95% CI) [c]			0.37 (0.16, 0.59)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	82.3	80.3	-2.0	75.0	76.7	1.7
		SD	19.01	22.53	12.63	14.78	15.87	11.39
		95% CI	73.4, 91.2	69.8, 90.9	-7.9, 3.9	51.5, 98.5	51.4, 101.9	-16.5, 19.8
		Median	86.7	86.7	0.0	73.3	70.0	3.3
		Q1, Q3	66.7, 100.0	73.3, 100.0	-6.7, 3.3	63.3, 86.7	66.7, 86.7	-6.7, 10.0
		Min, Max	46.7, 100.0	20.0, 100.0	-26.7, 20.0	60.0, 93.3	66.7, 100.0	-13.3, 13.3
		Mean Diff (95% CI) [a]			-2.0 (-7.9, 3.9)			1.7 (-16.5, 19.8)
		P-value [a]			0.487			0.789
		Mean Diff (95% CI) [b]			-3.7 (-17.8, 10.5)			
		P-value [b]			0.597			
		Effect Size (95% CI) [c]			-0.18 (-0.40, 0.03)			
	C21D1	N	18	18	18	4	4	4
		Mean	80.4	82.6	2.2	75.0	75.0	0.0
		SD	19.06	20.34	12.10	14.78	14.78	14.40
		95% CI	70.9, 89.8	72.5, 92.7	-3.8, 8.2	51.5, 98.5	51.5, 98.5	-22.9, 22.9
		Median	86.7	86.7	0.0	73.3	73.3	3.3
		Q1, Q3	66.7, 100.0	73.3, 100.0	0.0, 13.3	63.3, 86.7	63.3, 86.7	-10.0, 10.0
		Min, Max	46.7, 100.0	40.0, 100.0	-33.3, 20.0	60.0, 93.3	60.0, 93.3	-20.0, 13.3
		Mean Diff (95% CI) [a]			2.2 (-3.8, 8.2)			0.0 (-22.9, 22.9)
		P-value [a]			0.447			1.000
		Mean Diff (95% CI) [b]			2.2 (-12.2, 16.6)			
		P-value [b]			0.751			
		Effect Size (95% CI) [c]			0.11 (-0.10, 0.32)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	14	14	14	3	3	3
		Mean	77.6	79.0	1.4	73.3	80.0	6.7
		SD	19.50	23.51	16.78	17.64	17.64	0.00
		95% CI	66.4, 88.9	65.5, 92.6	-8.3, 11.1	29.5, 117.1	36.2, 123.8	6.7, 6.7
		Median	83.3	86.7	0.0	66.7	73.3	6.7
		Q1, Q3	60.0, 93.3	66.7, 100.0	0.0, 13.3	60.0, 93.3	66.7, 100.0	6.7, 6.7
		Min, Max	46.7, 100.0	33.3, 100.0	-46.7, 20.0	60.0, 93.3	66.7, 100.0	6.7, 6.7
		Mean Diff (95% CI) [a]			1.4 (-8.3, 11.1)			6.7 (6.7, 6.7)
		P-value [a]			0.755			<.001
		Mean Diff (95% CI) [b]			-5.2 (-26.4, 15.9)			
		P-value [b]			0.606			
		Effect Size (95% CI) [c]			-0.26 (-0.48, -0.05)			
	C23D1	N	11	11	11	3	3	3
		Mean	74.5	78.8	4.2	73.3	82.2	8.9
		SD	20.62	21.04	11.65	17.64	16.78	3.85
		95% CI	60.7, 88.4	64.7, 92.9	-3.6, 12.1	29.5, 117.1	40.5, 123.9	-0.7, 18.5
		Median	80.0	86.7	0.0	66.7	80.0	6.7
		Q1, Q3	53.3, 93.3	66.7, 100.0	-6.7, 20.0	60.0, 93.3	66.7, 100.0	6.7, 13.3
		Min, Max	46.7, 100.0	33.3, 100.0	-13.3, 20.0	60.0, 93.3	66.7, 100.0	6.7, 13.3
		Mean Diff (95% CI) [a]			4.2 (-3.6, 12.1)			8.9 (-0.7, 18.5)
		P-value [a]			0.255			0.057
		Mean Diff (95% CI) [b]			-4.6 (-19.9, 10.6)			
		P-value [b]			0.520			
		Effect Size (95% CI) [c]			-0.23 (-0.45, -0.02)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	76.7	78.0	1.3	80.0	83.3	3.3
		SD	20.43	24.95	11.67	18.86	14.14	4.71
		95% CI	62.1, 91.3	60.1, 95.9	-7.0, 9.7	-89.4, 249.4	-43.7, 210.4	-39.0, 45.7
		Median	83.3	86.7	0.0	80.0	83.3	3.3
		Q1, Q3	60.0, 93.3	60.0, 93.3	0.0, 0.0	66.7, 93.3	73.3, 93.3	0.0, 6.7
		Min, Max	46.7, 100.0	26.7, 100.0	-20.0, 20.0	66.7, 93.3	73.3, 93.3	0.0, 6.7
		Mean Diff (95% CI) [a]			1.3 (-7.0, 9.7)			3.3 (-39.0, 45.7)
		P-value [a]			0.726			0.500
		Mean Diff (95% CI) [b]			-2.0 (-21.3, 17.3)			
		P-value [b]			0.822			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.11)			
	C25D1	N	9	9	9	0	0	0
		Mean	74.1	77.0	3.0	NE	NE	NE
		SD	19.85	20.03	9.49	NE	NE	NE
		95% CI	58.8, 89.3	61.6, 92.4	-4.3, 10.3	NE, NE	NE, NE	NE, NE
		Median	80.0	80.0	0.0	NE	NE	NE
		Q1, Q3	60.0, 86.7	66.7, 86.7	0.0, 6.7	NE, NE	NE, NE	NE, NE
		Min, Max	46.7, 100.0	46.7, 100.0	-13.3, 20.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			3.0 (-4.3, 10.3)			NE (NE, NE)
		P-value [a]			0.377			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	84.2	88.1	4.0	93.3	100.0	6.7
		SD	14.67	13.26	8.82	NE	NE	NE
		95% CI	71.9, 96.4	77.0, 99.2	-3.4, 11.3	NE, NE	NE, NE	NE, NE
		Median	86.7	90.0	0.0	93.3	100.0	6.7
		Q1, Q3	73.3, 96.7	86.7, 96.7	-0.8, 10.0	93.3, 93.3	100.0, 100.0	6.7, 6.7
		Min, Max	60.0, 100.0	58.3, 100.0	-6.7, 20.0	93.3, 93.3	100.0, 100.0	6.7, 6.7
		Mean Diff (95% CI) [a]			4.0 (-3.4, 11.3)			6.7 (NE, NE)
		P-value [a]			0.245			NE
		Mean Diff (95% CI) [b]			-2.7 (-24.8, 19.4)			
		P-value [b]			0.780			
		Effect Size (95% CI) [c]			-0.14 (-0.35, 0.08)			
	C27D1	N	8	8	8	1	1	1
		Mean	84.2	88.3	4.2	93.3	100.0	6.7
		SD	14.67	9.26	12.31	NE	NE	NE
		95% CI	71.9, 96.4	80.6, 96.1	-6.1, 14.5	NE, NE	NE, NE	NE, NE
		Median	86.7	86.7	0.0	93.3	100.0	6.7
		Q1, Q3	73.3, 96.7	83.3, 96.7	-3.3, 16.7	93.3, 93.3	100.0, 100.0	6.7, 6.7
		Min, Max	60.0, 100.0	73.3, 100.0	-13.3, 20.0	93.3, 93.3	100.0, 100.0	6.7, 6.7
		Mean Diff (95% CI) [a]			4.2 (-6.1, 14.5)			6.7 (NE, NE)
		P-value [a]			0.370			NE
		Mean Diff (95% CI) [b]			-2.5 (-33.4, 28.4)			
		P-value [b]			0.854			
		Effect Size (95% CI) [c]			-0.13 (-0.34, 0.09)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	83.8	87.6	3.8	93.3	93.3	0.0
		SD	15.80	8.97	9.32	NE	NE	NE
		95% CI	69.2, 98.4	79.3, 95.9	-4.8, 12.4	NE, NE	NE, NE	NE, NE
		Median	86.7	86.7	0.0	93.3	93.3	0.0
		Q1, Q3	66.7, 100.0	80.0, 93.3	-6.7, 13.3	93.3, 93.3	93.3, 93.3	0.0, 0.0
		Min, Max	60.0, 100.0	73.3, 100.0	-6.7, 13.3	93.3, 93.3	93.3, 93.3	0.0, 0.0
		Mean Diff (95% CI) [a]			3.8 (-4.8, 12.4)			0.0 (NE, NE)
		P-value [a]			0.321			NE
		Mean Diff (95% CI) [b]			3.8 (-20.6, 28.2)			
		P-value [b]			0.715			
		Effect Size (95% CI) [c]			0.19 (-0.02, 0.40)			
	C29D1	N	4	4	4	1	1	1
		Mean	75.0	81.7	6.7	93.3	60.0	-33.3
		SD	14.78	8.39	13.33	NE	NE	NE
		95% CI	51.5, 98.5	68.3, 95.0	-14.5, 27.9	NE, NE	NE, NE	NE, NE
		Median	73.3	80.0	13.3	93.3	60.0	-33.3
		Q1, Q3	63.3, 86.7	76.7, 86.7	0.0, 13.3	93.3, 93.3	60.0, 60.0	-33.3, -33.3
		Min, Max	60.0, 93.3	73.3, 93.3	-13.3, 13.3	93.3, 93.3	60.0, 60.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			6.7 (-14.5, 27.9)			-33.3 (NE, NE)
		P-value [a]			0.391			NE
		Mean Diff (95% CI) [b]			40.0 (-7.4, 87.4)			
		P-value [b]			0.075			
		Effect Size (95% CI) [c]			2.01 (1.75, 2.27)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	85.0	93.3	8.3	93.3	53.3	-40.0
		SD	14.78	7.70	13.74	NE	NE	NE
		95% CI	61.5, 108.5	81.1, 105.6	-13.5, 30.2	NE, NE	NE, NE	NE, NE
		Median	86.7	93.3	10.0	93.3	53.3	-40.0
		Q1, Q3	73.3, 96.7	86.7, 100.0	-3.3, 20.0	93.3, 93.3	53.3, 53.3	-40.0, -40.0
		Min, Max	66.7, 100.0	86.7, 100.0	-6.7, 20.0	93.3, 93.3	53.3, 53.3	-40.0, -40.0
		Mean Diff (95% CI) [a]			8.3 (-13.5, 30.2)			-40.0 (NE, NE)
		P-value [a]			0.312			NE
		Mean Diff (95% CI) [b]			48.3 (-0.6, 97.2)			
		P-value [b]			0.051			
		Effect Size (95% CI) [c]			2.43 (2.15, 2.71)			
	C31D1	N	2	2	2	1	1	1
		Mean	73.3	86.7	13.3	93.3	80.0	-13.3
		SD	9.43	9.43	0.00	NE	NE	NE
		95% CI	-11.4, 158.0	2.0, 171.4	13.3, 13.3	NE, NE	NE, NE	NE, NE
		Median	73.3	86.7	13.3	93.3	80.0	-13.3
		Q1, Q3	66.7, 80.0	80.0, 93.3	13.3, 13.3	93.3, 93.3	80.0, 80.0	-13.3, -13.3
		Min, Max	66.7, 80.0	80.0, 93.3	13.3, 13.3	93.3, 93.3	80.0, 80.0	-13.3, -13.3
		Mean Diff (95% CI) [a]			13.3 (13.3, 13.3)			-13.3 (NE, NE)
		P-value [a]			<.001			NE
		Mean Diff (95% CI) [b]			26.7 (26.7, 26.7)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			1.34 (1.11, 1.58)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	73.3	90.0	16.7	93.3	86.7	-6.7
		SD	9.43	4.71	4.71	NE	NE	NE
		95% CI	-11.4, 158.0	47.6, 132.4	-25.7, 59.0	NE, NE	NE, NE	NE, NE
		Median	73.3	90.0	16.7	93.3	86.7	-6.7
		Q1, Q3	66.7, 80.0	86.7, 93.3	13.3, 20.0	93.3, 93.3	86.7, 86.7	-6.7, -6.7
		Min, Max	66.7, 80.0	86.7, 93.3	13.3, 20.0	93.3, 93.3	86.7, 86.7	-6.7, -6.7
		Mean Diff (95% CI) [a]			16.7 (-25.7, 59.0)			-6.7 (NE, NE)
		P-value [a]			0.126			NE
		Mean Diff (95% CI) [b]			23.3 (-50.0, 96.7)			
		P-value [b]			0.154			
		Effect Size (95% CI) [c]			1.17 (0.94, 1.40)			
	C33D1	N	3	3	3	1	1	1
		Mean	82.2	91.1	8.9	93.3	86.7	-6.7
		SD	16.78	7.70	10.18	NE	NE	NE
		95% CI	40.5, 123.9	72.0, 110.2	-16.4, 34.2	NE, NE	NE, NE	NE, NE
		Median	80.0	86.7	6.7	93.3	86.7	-6.7
		Q1, Q3	66.7, 100.0	86.7, 100.0	0.0, 20.0	93.3, 93.3	86.7, 86.7	-6.7, -6.7
		Min, Max	66.7, 100.0	86.7, 100.0	0.0, 20.0	93.3, 93.3	86.7, 86.7	-6.7, -6.7
		Mean Diff (95% CI) [a]			8.9 (-16.4, 34.2)			-6.7 (NE, NE)
		P-value [a]			0.270			NE
		Mean Diff (95% CI) [b]			15.6 (-35.0, 66.1)			
		P-value [b]			0.317			
		Effect Size (95% CI) [c]			0.78 (0.56, 1.00)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	82.2	93.3	11.1	NE	NE	NE
		SD	16.78	11.55	10.18	NE	NE	NE
		95% CI	40.5, 123.9	64.6, 122.0	-14.2, 36.4	NE, NE	NE, NE	NE, NE
		Median	80.0	100.0	13.3	NE	NE	NE
		Q1, Q3	66.7, 100.0	80.0, 100.0	0.0, 20.0	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	80.0, 100.0	0.0, 20.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-14.2, 36.4)			NE (NE, NE)
		P-value [a]			0.199			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	73.3	80.0	6.7	NE	NE	NE
		SD	9.43	18.86	9.43	NE	NE	NE
		95% CI	-11.4, 158.0	-89.4, 249.4	-78.0, 91.4	NE, NE	NE, NE	NE, NE
		Median	73.3	80.0	6.7	NE	NE	NE
		Q1, Q3	66.7, 80.0	66.7, 93.3	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 80.0	66.7, 93.3	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			6.7 (-78.0, 91.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	82.2	88.9	6.7	NE	NE	NE
		SD	16.78	13.88	6.67	NE	NE	NE
		95% CI	40.5, 123.9	54.4, 123.4	-9.9, 23.2	NE, NE	NE, NE	NE, NE
		Median	80.0	93.3	6.7	NE	NE	NE
		Q1, Q3	66.7, 100.0	73.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	73.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			6.7 (-9.9, 23.2)			NE (NE, NE)
		P-value [a]			0.225			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	82.2	91.1	8.9	NE	NE	NE
		SD	16.78	10.18	7.70	NE	NE	NE
		95% CI	40.5, 123.9	65.8, 116.4	-10.2, 28.0	NE, NE	NE, NE	NE, NE
		Median	80.0	93.3	13.3	NE	NE	NE
		Q1, Q3	66.7, 100.0	80.0, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	80.0, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.9 (-10.2, 28.0)			NE (NE, NE)
		P-value [a]			0.184			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	90.0	96.7	6.7	NE	NE	NE
		SD	14.14	4.71	9.43	NE	NE	NE
		95% CI	-37.1, 217.1	54.3, 139.0	-78.0, 91.4	NE, NE	NE, NE	NE, NE
		Median	90.0	96.7	6.7	NE	NE	NE
		Q1, Q3	80.0, 100.0	93.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Min, Max	80.0, 100.0	93.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			6.7 (-78.0, 91.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	90.0	100.0	10.0	NE	NE	NE
		SD	14.14	0.00	14.14	NE	NE	NE
		95% CI	-37.1, 217.1	100.0, 100.0	-117.1, 137.1	NE, NE	NE, NE	NE, NE
		Median	90.0	100.0	10.0	NE	NE	NE
		Q1, Q3	80.0, 100.0	100.0, 100.0	0.0, 20.0	NE, NE	NE, NE	NE, NE
		Min, Max	80.0, 100.0	100.0, 100.0	0.0, 20.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			10.0 (-117.1, 137.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	90.0	96.7	6.7	NE	NE	NE
		SD	14.14	4.71	9.43	NE	NE	NE
		95% CI	-37.1, 217.1	54.3, 139.0	-78.0, 91.4	NE, NE	NE, NE	NE, NE
		Median	90.0	96.7	6.7	NE	NE	NE
		Q1, Q3	80.0, 100.0	93.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Min, Max	80.0, 100.0	93.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			6.7 (-78.0, 91.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	90.0	96.7	6.7	NE	NE	NE
		SD	14.14	4.71	9.43	NE	NE	NE
		95% CI	-37.1, 217.1	54.3, 139.0	-78.0, 91.4	NE, NE	NE, NE	NE, NE
		Median	90.0	96.7	6.7	NE	NE	NE
		Q1, Q3	80.0, 100.0	93.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Min, Max	80.0, 100.0	93.3, 100.0	0.0, 13.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			6.7 (-78.0, 91.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	80.0	80.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	80.0	80.0	0.0	NE	NE	NE
		Q1, Q3	80.0, 80.0	80.0, 80.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	80.0, 80.0	80.0, 80.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	80.0	86.7	6.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	80.0	86.7	6.7	NE	NE	NE
		Q1, Q3	80.0, 80.0	86.7, 86.7	6.7, 6.7	NE, NE	NE, NE	NE, NE
		Min, Max	80.0, 80.0	86.7, 86.7	6.7, 6.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			6.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	125	125	125
		Mean	79.2	73.3	-5.9	79.0	72.6	-6.4
		SD	20.19	25.58	17.69	19.60	23.61	18.93
		95% CI	75.7, 82.7	68.9, 77.7	-9.0, -2.8	75.5, 82.5	68.4, 76.8	-9.8, -3.1
		Median	86.7	80.0	0.0	86.7	80.0	-6.7
		Q1, Q3	66.7, 93.3	60.0, 93.3	-20.0, 6.7	66.7, 93.3	60.0, 86.7	-13.3, 0.0
		Min, Max	20.0, 100.0	0.0, 100.0	-73.3, 33.3	6.7, 100.0	0.0, 100.0	-80.0, 46.7
		Mean Diff (95% CI) [a]			-5.9 (-9.0, -2.8)			-6.4 (-9.8, -3.1)
		P-value [a]			<.001			<.001
		Mean Diff (95% CI) [b]			0.5 (-4.0, 5.0)			
		P-value [b]			0.825			
		Effect Size (95% CI) [c]			0.03 (-0.19, 0.24)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	86.7	77.6	-9.0	80.7	63.0	-17.8
		SD	10.78	17.85	15.60	12.67	30.57	24.27
		95% CI	80.4, 92.9	67.3, 87.9	-18.1, 0.0	71.0, 90.5	39.5, 86.5	-36.4, 0.9
		Median	86.7	80.0	-6.7	80.0	73.3	-13.3
		Q1, Q3	80.0, 93.3	80.0, 86.7	-20.0, 0.0	80.0, 86.7	60.0, 80.0	-20.0, 0.0
		Min, Max	66.7, 100.0	33.3, 100.0	-40.0, 20.0	53.3, 100.0	6.7, 100.0	-73.3, 6.7
		Mean Diff (95% CI) [a]			-9.0 (-18.1, 0.0)			-17.8 (-36.4, 0.9)
		P-value [a]			0.049			0.059
		Mean Diff (95% CI) [b]			8.7 (-8.5, 25.9)			
		P-value [b]			0.303			
		Effect Size (95% CI) [c]			0.44 (0.22, 0.65)			
Role Functioning	Baseline	N	174			164		
		Mean	76.1			76.3		
		SD	25.99			25.78		
		95% CI	72.2, 79.9			72.3, 80.3		
		Median	83.3			83.3		
		Q1, Q3	66.7, 100.0			66.7, 100.0		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	143	144	143
		Mean	77.2	71.6	-5.6	77.3	72.2	-5.0
		SD	25.50	29.52	26.30	25.45	27.52	23.57
		Median	83.3	66.7	0.0	83.3	66.7	0.0
		95% CI	73.1, 81.3	66.9, 76.3	-9.8, -1.4	73.1, 81.5	67.7, 76.8	-8.9, -1.1
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 0.0	66.7, 100.0	50.0, 100.0	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-5.6 (-9.8, -1.4)			-5.0 (-8.9, -1.1)
		P-value [a]			0.010			0.012
		Mean Diff (95% CI) [b]			-0.6 (-6.3, 5.2)			
		P-value [b]			0.842			
		Effect Size (95% CI) [c]			-0.02 (-0.24, 0.19)			
	C3D1	N	124	124	124	101	101	101
		Mean	78.6	73.9	-4.7	78.4	72.8	-5.6
		SD	23.81	26.22	25.29	21.28	23.18	20.85
		Median	83.3	75.0	0.0	83.3	66.7	0.0
		95% CI	74.4, 82.9	69.3, 78.6	-9.2, -0.2	74.2, 82.6	68.2, 77.3	-9.7, -1.5
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 0.0	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-100.0, 66.7	16.7, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-4.7 (-9.2, -0.2)			-5.6 (-9.7, -1.5)
		P-value [a]			0.040			0.008
		Mean Diff (95% CI) [b]			0.9 (-5.3, 7.1)			
		P-value [b]			0.773			
		Effect Size (95% CI) [c]			0.03 (-0.18, 0.25)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	93	94	93
		Mean	77.8	76.9	-0.9	77.4	73.4	-3.4
		SD	24.44	27.60	24.49	21.65	25.20	22.33
		Median	83.3	83.3	0.0	66.7	66.7	0.0
		95% CI	73.3, 82.4	71.8, 82.1	-5.5, 3.7	73.0, 81.9	68.2, 78.6	-8.0, 1.2
		Q1, Q3	66.7, 100.0	66.7, 100.0	-8.3, 8.3	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-100.0, 66.7	16.7, 100.0	16.7, 100.0	-50.0, 50.0
		Mean Diff (95% CI) [a]			-0.9 (-5.5, 3.7)			-3.4 (-8.0, 1.2)
		P-value [a]			0.700			0.145
		Mean Diff (95% CI) [b]			2.5 (-4.0, 9.0)			
		P-value [b]			0.448			
		Effect Size (95% CI) [c]			0.10 (-0.12, 0.31)			
	C5D1	N	97	97	97	79	79	79
		Mean	79.0	75.6	-3.4	78.1	73.0	-5.1
		SD	23.85	25.69	22.04	21.44	22.85	19.68
		Median	83.3	83.3	0.0	83.3	66.7	0.0
		95% CI	74.2, 83.8	70.4, 80.8	-7.9, 1.0	73.3, 82.9	67.9, 78.1	-9.5, -0.7
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 0.0	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-50.0, 66.7	16.7, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-3.4 (-7.9, 1.0)			-5.1 (-9.5, -0.7)
		P-value [a]			0.128			0.025
		Mean Diff (95% CI) [b]			1.6 (-4.7, 7.9)			
		P-value [b]			0.610			
		Effect Size (95% CI) [c]			0.06 (-0.15, 0.28)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	68	69	68
		Mean	80.4	81.1	0.7	80.1	70.3	-9.3
		SD	22.68	24.97	23.68	20.00	27.25	23.11
		Median	83.3	100.0	0.0	83.3	66.7	0.0
		95% CI	75.8, 85.0	76.0, 86.1	-4.1, 5.5	75.3, 85.0	63.7, 76.8	-14.9, -3.7
		Q1, Q3	66.7, 100.0	66.7, 100.0	-8.3, 16.7	66.7, 100.0	50.0, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-100.0, 66.7	16.7, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			0.7 (-4.1, 5.5)			-9.3 (-14.9, -3.7)
		P-value [a]			0.775			0.001
		Mean Diff (95% CI) [b]			10.0 (2.7, 17.3)			
		P-value [b]			0.008			
		Effect Size (95% CI) [c]			0.39 (0.17, 0.60)			
	C7D1	N	79	79	79	52	53	52
		Mean	78.3	78.1	-0.2	79.2	75.2	-3.2
		SD	24.80	24.25	22.88	21.61	22.56	22.88
		Median	83.3	83.3	0.0	83.3	66.7	0.0
		95% CI	72.7, 83.8	72.6, 83.5	-5.3, 4.9	73.2, 85.2	68.9, 81.4	-9.6, 3.2
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-50.0, 66.7	16.7, 100.0	33.3, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-0.2 (-5.3, 4.9)			-3.2 (-9.6, 3.2)
		P-value [a]			0.935			0.317
		Mean Diff (95% CI) [b]			3.0 (-5.1, 11.1)			
		P-value [b]			0.465			
		Effect Size (95% CI) [c]			0.12 (-0.10, 0.33)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	49	50	49
		Mean	78.3	78.1	-0.2	80.3	74.0	-5.4
		SD	24.50	27.11	22.69	21.96	24.78	24.39
		Median	83.3	83.3	0.0	83.3	66.7	0.0
		95% CI	72.7, 83.9	71.9, 84.3	-5.4, 5.0	74.0, 86.6	67.0, 81.0	-12.4, 1.6
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	16.7, 100.0	0.0, 100.0	-66.7, 50.0
		Mean Diff (95% CI) [a]			-0.2 (-5.4, 5.0)			-5.4 (-12.4, 1.6)
		P-value [a]			0.933			0.125
		Mean Diff (95% CI) [b]			5.2 (-3.3, 13.7)			
		P-value [b]			0.225			
		Effect Size (95% CI) [c]			0.20 (-0.01, 0.41)			
	C9D1	N	60	60	60	41	42	41
		Mean	80.3	76.9	-3.3	79.7	74.6	-4.1
		SD	23.06	26.59	24.12	22.83	23.64	20.68
		Median	83.3	83.3	0.0	83.3	75.0	0.0
		95% CI	74.3, 86.2	70.1, 83.8	-9.6, 2.9	72.5, 86.9	67.2, 82.0	-10.6, 2.5
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 0.0	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-100.0, 50.0	16.7, 100.0	33.3, 100.0	-66.7, 50.0
		Mean Diff (95% CI) [a]			-3.3 (-9.6, 2.9)			-4.1 (-10.6, 2.5)
		P-value [a]			0.289			0.215
		Mean Diff (95% CI) [b]			0.7 (-8.4, 9.9)			
		P-value [b]			0.874			
		Effect Size (95% CI) [c]			0.03 (-0.18, 0.24)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	29	30	29
		Mean	79.0	79.3	0.3	77.6	70.6	-6.9
		SD	22.94	23.78	22.31	21.02	23.85	22.06
		Median	83.3	91.7	0.0	83.3	66.7	0.0
		95% CI	72.8, 85.3	72.8, 85.8	-5.8, 6.4	69.6, 85.6	61.7, 79.5	-15.3, 1.5
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 83.3	-16.7, 0.0
		Min, Max	16.7, 100.0	16.7, 100.0	-66.7, 50.0	33.3, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			0.3 (-5.8, 6.4)			-6.9 (-15.3, 1.5)
		P-value [a]			0.919			0.103
		Mean Diff (95% CI) [b]			7.2 (-3.0, 17.4)			
		P-value [b]			0.163			
		Effect Size (95% CI) [c]			0.28 (0.06, 0.49)			
	C11D1	N	46	46	46	23	23	23
		Mean	77.9	77.5	-0.4	81.9	73.9	-8.0
		SD	23.58	24.65	23.44	20.67	24.53	28.37
		Median	83.3	83.3	0.0	83.3	66.7	0.0
		95% CI	70.9, 84.9	70.2, 84.9	-7.3, 6.6	72.9, 90.8	63.3, 84.5	-20.2, 4.3
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	33.3, 100.0	-66.7, 50.0	33.3, 100.0	0.0, 100.0	-100.0, 33.3
		Mean Diff (95% CI) [a]			-0.4 (-7.3, 6.6)			-8.0 (-20.2, 4.3)
		P-value [a]			0.917			0.192
		Mean Diff (95% CI) [b]			7.6 (-5.2, 20.4)			
		P-value [b]			0.241			
		Effect Size (95% CI) [c]			0.29 (0.08, 0.51)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	78.9	77.6	-1.2	85.1	78.9	-6.1
		SD	24.16	25.44	23.39	18.34	24.12	23.71
		Median	83.3	83.3	0.0	83.3	83.3	0.0
		95% CI	71.2, 86.5	69.6, 85.7	-8.6, 6.2	76.2, 93.9	67.3, 90.6	-17.6, 5.3
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 0.0	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-50.0, 50.0	33.3, 100.0	33.3, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-1.2 (-8.6, 6.2)			-6.1 (-17.6, 5.3)
		P-value [a]			0.740			0.274
		Mean Diff (95% CI) [b]			4.9 (-8.1, 18.0)			
		P-value [b]			0.453			
		Effect Size (95% CI) [c]			0.19 (-0.02, 0.40)			
	C13D1	N	32	32	32	15	15	15
		Mean	79.7	79.2	-0.5	81.1	73.3	-7.8
		SD	24.59	22.00	23.75	19.79	21.64	19.79
		Median	83.3	83.3	0.0	83.3	66.7	0.0
		95% CI	70.8, 88.6	71.2, 87.1	-9.1, 8.0	70.2, 92.1	61.3, 85.3	-18.7, 3.2
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-33.3, 0.0
		Min, Max	16.7, 100.0	33.3, 100.0	-50.0, 50.0	33.3, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-0.5 (-9.1, 8.0)			-7.8 (-18.7, 3.2)
		P-value [a]			0.902			0.150
		Mean Diff (95% CI) [b]			7.3 (-7.0, 21.5)			
		P-value [b]			0.310			
		Effect Size (95% CI) [c]			0.28 (0.07, 0.49)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	78.8	80.8	2.0	77.8	73.6	-4.2
		SD	24.03	23.61	20.31	20.52	24.06	25.75
		Median	83.3	83.3	0.0	75.0	66.7	0.0
		95% CI	70.3, 87.3	72.4, 89.2	-5.2, 9.2	64.7, 90.8	58.3, 88.9	-20.5, 12.2
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-8.3, 8.3
		Min, Max	16.7, 100.0	0.0, 100.0	-50.0, 50.0	33.3, 100.0	33.3, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			2.0 (-5.2, 9.2)			-4.2 (-20.5, 12.2)
		P-value [a]			0.572			0.586
		Mean Diff (95% CI) [b]			6.2 (-8.7, 21.0)			
		P-value [b]			0.405			
		Effect Size (95% CI) [c]			0.24 (0.02, 0.45)			
	C15D1	N	28	28	28	13	13	13
		Mean	78.0	73.2	-4.8	79.5	70.5	-9.0
		SD	24.87	25.80	27.91	20.59	22.72	26.01
		Median	83.3	66.7	0.0	83.3	66.7	0.0
		95% CI	68.3, 87.6	63.2, 83.2	-15.6, 6.1	67.0, 91.9	56.8, 84.2	-24.7, 6.7
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 8.3	66.7, 100.0	66.7, 83.3	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	33.3, 100.0	33.3, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-4.8 (-15.6, 6.1)			-9.0 (-24.7, 6.7)
		P-value [a]			0.375			0.237
		Mean Diff (95% CI) [b]			4.2 (-14.3, 22.8)			
		P-value [b]			0.649			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.38)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	78.0	74.4	-3.6	80.0	76.7	-3.3
		SD	25.28	27.02	25.40	23.31	21.08	20.49
		Median	83.3	75.0	0.0	83.3	75.0	0.0
		95% CI	68.2, 87.8	63.9, 84.9	-13.4, 6.3	63.3, 96.7	61.6, 91.7	-18.0, 11.3
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 8.3	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-50.0, 50.0	33.3, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-3.6 (-13.4, 6.3)			-3.3 (-18.0, 11.3)
		P-value [a]			0.463			0.619
		Mean Diff (95% CI) [b]			-0.2 (-18.4, 17.9)			
		P-value [b]			0.979			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.20)			
	C17D1	N	26	26	26	7	7	7
		Mean	78.2	74.4	-3.8	71.4	71.4	0.0
		SD	25.28	29.15	28.01	23.00	23.00	27.22
		Median	83.3	83.3	0.0	66.7	66.7	0.0
		95% CI	68.0, 88.4	62.6, 86.1	-15.2, 7.5	50.2, 92.7	50.2, 92.7	-25.2, 25.2
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-33.3, 33.3
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	33.3, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-3.8 (-15.2, 7.5)			0.0 (-25.2, 25.2)
		P-value [a]			0.490			1.000
		Mean Diff (95% CI) [b]			-3.8 (-28.0, 20.3)			
		P-value [b]			0.748			
		Effect Size (95% CI) [c]			-0.15 (-0.36, 0.06)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	75.8	72.7	-3.0	81.0	76.2	-4.8
		SD	26.09	31.09	29.83	17.82	18.90	15.85
		Median	83.3	83.3	0.0	66.7	66.7	0.0
		95% CI	64.2, 87.3	58.9, 86.5	-16.3, 10.2	64.5, 97.4	58.7, 93.7	-19.4, 9.9
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	66.7, 100.0	50.0, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			-3.0 (-16.3, 10.2)			-4.8 (-19.4, 9.9)
		P-value [a]			0.639			0.457
		Mean Diff (95% CI) [b]			1.7 (-22.6, 26.1)			
		P-value [b]			0.885			
		Effect Size (95% CI) [c]			0.07 (-0.15, 0.28)			
	C19D1	N	20	20	20	6	6	6
		Mean	75.8	75.0	-0.8	83.3	69.4	-13.9
		SD	26.20	26.77	23.86	18.26	30.58	34.02
		Median	83.3	66.7	0.0	83.3	75.0	-8.3
		95% CI	63.6, 88.1	62.5, 87.5	-12.0, 10.3	64.2, 102.5	37.4, 101.5	-49.6, 21.8
		Q1, Q3	66.7, 100.0	66.7, 100.0	-25.0, 16.7	66.7, 100.0	33.3, 100.0	-33.3, 0.0
		Min, Max	16.7, 100.0	16.7, 100.0	-33.3, 50.0	66.7, 100.0	33.3, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-0.8 (-12.0, 10.3)			-13.9 (-49.6, 21.8)
		P-value [a]			0.878			0.363
		Mean Diff (95% CI) [b]			13.1 (-12.2, 38.3)			
		P-value [b]			0.297			
		Effect Size (95% CI) [c]			0.50 (0.29, 0.72)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	78.3	69.2	-9.2	83.3	79.2	-4.2
		SD	27.09	30.72	23.86	19.25	15.96	20.97
		Median	83.3	75.0	-8.3	83.3	75.0	0.0
		95% CI	65.7, 91.0	54.8, 83.5	-20.3, 2.0	52.7, 114.0	53.8, 104.6	-37.5, 29.2
		Q1, Q3	66.7, 100.0	66.7, 91.7	-16.7, 0.0	66.7, 100.0	66.7, 91.7	-16.7, 8.3
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	66.7, 100.0	66.7, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			-9.2 (-20.3, 2.0)			-4.2 (-37.5, 29.2)
		P-value [a]			0.102			0.718
		Mean Diff (95% CI) [b]			-5.0 (-31.7, 21.7)			
		P-value [b]			0.701			
		Effect Size (95% CI) [c]			-0.19 (-0.41, 0.02)			
	C21D1	N	18	18	18	4	4	4
		Mean	75.9	75.0	-0.9	83.3	75.0	-8.3
		SD	27.55	29.84	26.49	19.25	16.67	16.67
		Median	83.3	83.3	0.0	83.3	66.7	0.0
		95% CI	62.2, 89.6	60.2, 89.8	-14.1, 12.2	52.7, 114.0	48.5, 101.5	-34.9, 18.2
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 83.3	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	66.7, 100.0	66.7, 100.0	-33.3, 0.0
		Mean Diff (95% CI) [a]			-0.9 (-14.1, 12.2)			-8.3 (-34.9, 18.2)
		P-value [a]			0.884			0.391
		Mean Diff (95% CI) [b]			7.4 (-21.7, 36.5)			
		P-value [b]			0.602			
		Effect Size (95% CI) [c]			0.29 (0.07, 0.50)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	14	14	14	3	3	3
		Mean	76.2	77.4	1.2	77.8	77.8	0.0
		SD	30.46	24.11	23.99	19.25	19.25	0.00
		Median	83.3	75.0	0.0	66.7	66.7	0.0
		95% CI	58.6, 93.8	63.5, 91.3	-12.7, 15.0	30.0, 125.6	30.0, 125.6	0.0, 0.0
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 50.0	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			1.2 (-12.7, 15.0)			0.0 (0.0, 0.0)
		P-value [a]			0.856			NE
		Mean Diff (95% CI) [b]			1.2 (-29.1, 31.5)			
		P-value [b]			0.934			
		Effect Size (95% CI) [c]			0.05 (-0.17, 0.26)			
	C23D1	N	11	11	11	3	3	3
		Mean	72.7	74.2	1.5	77.8	77.8	0.0
		SD	33.56	32.80	21.67	19.25	19.25	0.00
		Median	83.3	83.3	0.0	66.7	66.7	0.0
		95% CI	50.2, 95.3	52.2, 96.3	-13.0, 16.1	30.0, 125.6	30.0, 125.6	0.0, 0.0
		Q1, Q3	33.3, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-33.3, 50.0	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			1.5 (-13.0, 16.1)			0.0 (0.0, 0.0)
		P-value [a]			0.821			NE
		Mean Diff (95% CI) [b]			1.5 (-26.6, 29.6)			
		P-value [b]			0.908			
		Effect Size (95% CI) [c]			0.06 (-0.15, 0.27)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	78.3	73.3	-5.0	83.3	83.3	0.0
		SD	29.45	33.52	13.72	23.57	23.57	0.00
		Median	83.3	83.3	-8.3	83.3	83.3	0.0
		95% CI	57.3, 99.4	49.4, 97.3	-14.8, 4.8	-128.4, 295.1	-128.4, 295.1	0.0, 0.0
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 0.0	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-5.0 (-14.8, 4.8)			0.0 (0.0, 0.0)
		P-value [a]			0.279			NE
		Mean Diff (95% CI) [b]			-5.0 (-27.5, 17.5)			
		P-value [b]			0.631			
		Effect Size (95% CI) [c]			-0.19 (-0.41, 0.02)			
	C25D1	N	9	9	9	0	0	0
		Mean	75.9	66.7	-9.3	NE	NE	NE
		SD	30.17	32.27	14.70	NE	NE	NE
		Median	83.3	66.7	-16.7	NE	NE	NE
		95% CI	52.7, 99.1	41.9, 91.5	-20.6, 2.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	66.7, 83.3	-16.7, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	16.7, 100.0	0.0, 100.0	-33.3, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-9.3 (-20.6, 2.0)			NE (NE, NE)
		P-value [a]			0.095			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	91.7	70.8	-20.8	100.0	100.0	0.0
		SD	8.91	31.81	33.03	NE	NE	NE
		Median	91.7	75.0	-8.3	100.0	100.0	0.0
		95% CI	84.2, 99.1	44.2, 97.4	-48.5, 6.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	50.0, 100.0	-41.7, 0.0	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	83.3, 100.0	16.7, 100.0	-83.3, 16.7	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-20.8 (-48.5, 6.8)			0.0 (NE, NE)
		P-value [a]			0.118			NE
		Mean Diff (95% CI) [b]			-20.8 (-103.7, 62.0)			
		P-value [b]			0.571			
		Effect Size (95% CI) [c]			-0.80 (-1.02, -0.58)			
	C27D1	N	8	8	8	1	1	1
		Mean	91.7	91.7	0.0	100.0	100.0	0.0
		SD	8.91	12.60	17.82	NE	NE	NE
		Median	91.7	100.0	0.0	100.0	100.0	0.0
		95% CI	84.2, 99.1	81.1, 102.2	-14.9, 14.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	83.3, 100.0	-8.3, 16.7	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	83.3, 100.0	66.7, 100.0	-33.3, 16.7	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (-14.9, 14.9)			0.0 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			0.0 (-44.7, 44.7)			
		P-value [b]			1.000			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	92.9	85.7	-7.1	100.0	100.0	0.0
		SD	8.91	15.00	16.27	NE	NE	NE
		Median	100.0	83.3	0.0	100.0	100.0	0.0
		95% CI	84.6, 101.1	71.8, 99.6	-22.2, 7.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 0.0	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	83.3, 100.0	66.7, 100.0	-33.3, 16.7	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-7.1 (-22.2, 7.9)			0.0 (NE, NE)
		P-value [a]			0.289			NE
		Mean Diff (95% CI) [b]			-7.1 (-49.7, 35.4)			
		P-value [b]			0.695			
		Effect Size (95% CI) [c]			-0.28 (-0.49, -0.06)			
	C29D1	N	4	4	4	1	1	1
		Mean	87.5	75.0	-12.5	100.0	50.0	-50.0
		SD	8.33	16.67	20.97	NE	NE	NE
		Median	83.3	66.7	-16.7	100.0	50.0	-50.0
		95% CI	74.2, 100.8	48.5, 101.5	-45.9, 20.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 91.7	66.7, 83.3	-25.0, 0.0	100.0, 100.0	50.0, 50.0	-50.0, -50.0
		Min, Max	83.3, 100.0	66.7, 100.0	-33.3, 16.7	100.0, 100.0	50.0, 50.0	-50.0, -50.0
		Mean Diff (95% CI) [a]			-12.5 (-45.9, 20.9)			-50.0 (NE, NE)
		P-value [a]			0.319			NE
		Mean Diff (95% CI) [b]			37.5 (-37.1, 112.1)			
		P-value [b]			0.208			
		Effect Size (95% CI) [c]			1.45 (1.21, 1.68)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	91.7	91.7	0.0	100.0	33.3	-66.7
		SD	9.62	16.67	23.57	NE	NE	NE
		Median	91.7	100.0	8.3	100.0	33.3	-66.7
		95% CI	76.4, 107.0	65.1, 118.2	-37.5, 37.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	83.3, 100.0	-16.7, 16.7	100.0, 100.0	33.3, 33.3	-66.7, -66.7
		Min, Max	83.3, 100.0	66.7, 100.0	-33.3, 16.7	100.0, 100.0	33.3, 33.3	-66.7, -66.7
		Mean Diff (95% CI) [a]			0.0 (-37.5, 37.5)			-66.7 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			66.7 (-17.2, 150.5)			
		P-value [b]			0.085			
		Effect Size (95% CI) [c]			2.57 (2.28, 2.86)			
	C31D1	N	2	2	2	1	1	1
		Mean	83.3	83.3	0.0	100.0	66.7	-33.3
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	83.3	83.3	0.0	100.0	66.7	-33.3
		95% CI	83.3, 83.3	-128.4, 295.1	-211.8, 211.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	66.7, 100.0	-16.7, 16.7	100.0, 100.0	66.7, 66.7	-33.3, -33.3
		Min, Max	83.3, 83.3	66.7, 100.0	-16.7, 16.7	100.0, 100.0	66.7, 66.7	-33.3, -33.3
		Mean Diff (95% CI) [a]			0.0 (-211.8, 211.8)			-33.3 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			33.3 (-333.5, 400.1)			
		P-value [b]			0.454			
		Effect Size (95% CI) [c]			1.28 (1.05, 1.52)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	83.3	91.7	8.3	100.0	100.0	0.0
		SD	0.00	11.79	11.79	NE	NE	NE
		Median	83.3	91.7	8.3	100.0	100.0	0.0
		95% CI	83.3, 83.3	-14.2, 197.6	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	83.3, 100.0	0.0, 16.7	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	83.3, 83.3	83.3, 100.0	0.0, 16.7	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			0.0 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			8.3 (-175.1, 191.7)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			0.32 (0.11, 0.54)			
	C33D1	N	3	3	3	1	1	1
		Mean	88.9	88.9	0.0	100.0	83.3	-16.7
		SD	9.62	19.25	16.67	NE	NE	NE
		Median	83.3	100.0	0.0	100.0	83.3	-16.7
		95% CI	65.0, 112.8	41.1, 136.7	-41.4, 41.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 16.7	100.0, 100.0	83.3, 83.3	-16.7, -16.7
		Min, Max	83.3, 100.0	66.7, 100.0	-16.7, 16.7	100.0, 100.0	83.3, 83.3	-16.7, -16.7
		Mean Diff (95% CI) [a]			0.0 (-41.4, 41.4)			-16.7 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			16.7 (-66.1, 99.5)			
		P-value [b]			0.478			
		Effect Size (95% CI) [c]			0.64 (0.42, 0.86)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	88.9	88.9	0.0	NE	NE	NE
		SD	9.62	19.25	16.67	NE	NE	NE
		Median	83.3	100.0	0.0	NE	NE	NE
		95% CI	65.0, 112.8	41.1, 136.7	-41.4, 41.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (-41.4, 41.4)			NE (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	83.3	83.3	0.0	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	83.3	83.3	0.0	NE	NE	NE
		95% CI	83.3, 83.3	-128.4, 295.1	-211.8, 211.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (-211.8, 211.8)			NE (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	88.9	88.9	0.0	NE	NE	NE
		SD	9.62	19.25	16.67	NE	NE	NE
		Median	83.3	100.0	0.0	NE	NE	NE
		95% CI	65.0, 112.8	41.1, 136.7	-41.4, 41.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (-41.4, 41.4)			NE (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	88.9	88.9	0.0	NE	NE	NE
		SD	9.62	19.25	16.67	NE	NE	NE
		Median	83.3	100.0	0.0	NE	NE	NE
		95% CI	65.0, 112.8	41.1, 136.7	-41.4, 41.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	66.7, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (-41.4, 41.4)			NE (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	91.7	100.0	8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	91.7	100.0	8.3	NE	NE	NE
		95% CI	-14.2, 197.6	100.0, 100.0	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	91.7	100.0	8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	91.7	100.0	8.3	NE	NE	NE
		95% CI	-14.2, 197.6	100.0, 100.0	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	91.7	100.0	8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	91.7	100.0	8.3	NE	NE	NE
		95% CI	-14.2, 197.6	100.0, 100.0	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	91.7	83.3	-8.3	NE	NE	NE
		SD	11.79	23.57	11.79	NE	NE	NE
		Median	91.7	83.3	-8.3	NE	NE	NE
		95% CI	-14.2, 197.6	-128.4, 295.1	-114.2, 97.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	66.7, 100.0	-16.7, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-8.3 (-114.2, 97.6)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	83.3	100.0	16.7	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	83.3	100.0	16.7	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	124	125	124
		Mean	74.9	66.4	-8.5	78.0	65.1	-12.6
		SD	27.22	33.59	29.70	25.02	31.07	28.54
		Median	83.3	66.7	0.0	83.3	66.7	0.0
		95% CI	70.2, 79.6	60.6, 72.2	-13.7, -3.4	73.5, 82.4	59.6, 70.6	-17.7, -7.6
		Q1, Q3	66.7, 100.0	33.3, 100.0	-33.3, 16.7	66.7, 100.0	50.0, 100.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			-8.5 (-13.7, -3.4)			-12.6 (-17.7, -7.6)
		P-value [a]			0.001			<.001
		Mean Diff (95% CI) [b]			4.1 (-3.1, 11.3)			
		P-value [b]			0.261			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	82.1	73.8	-8.3	87.0	59.3	-27.8
		SD	22.13	24.21	19.34	13.89	37.37	36.32
		Median	91.7	66.7	0.0	83.3	66.7	-16.7
		95% CI	69.4, 94.9	59.8, 87.8	-19.5, 2.8	76.4, 97.7	30.5, 88.0	-55.7, 0.1
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 0.0	83.3, 100.0	50.0, 83.3	-33.3, 0.0
		Min, Max	33.3, 100.0	33.3, 100.0	-50.0, 16.7	66.7, 100.0	0.0, 100.0	-100.0, 16.7
		Mean Diff (95% CI) [a]			-8.3 (-19.5, 2.8)			-27.8 (-55.7, 0.1)
		P-value [a]			0.131			0.051
		Mean Diff (95% CI) [b]			19.4 (-4.6, 43.5)			
		P-value [b]			0.108			
		Effect Size (95% CI) [c]			0.75 (0.53, 0.97)			
Emotional Functioning	Baseline	N	174			165		
		Mean	71.5			74.4		
		SD	25.43			21.39		
		Median	75.0			83.3		
		95% CI	67.7, 75.3			71.2, 77.7		
		Q1, Q3	58.3, 91.7			66.7, 91.7		
		Min, Max	0.0, 100.0			8.3, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	72.5	78.6	6.1	74.8	76.7	1.9
		SD	25.78	22.89	20.66	21.56	23.04	17.70
		95% CI	68.4, 76.6	74.9, 82.3	2.8, 9.4	71.3, 78.4	72.9, 80.5	-1.1, 4.8
		Median	83.3	83.3	0.0	83.3	83.3	0.0
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 16.7	66.7, 91.7	66.7, 100.0	-8.3, 8.3
		Min, Max	0.0, 100.0	0.0, 100.0	-58.3, 75.0	8.3, 100.0	0.0, 100.0	-66.7, 50.0
		Mean Diff (95% CI) [a]			6.1 (2.8, 9.4)			1.9 (-1.1, 4.8)
		P-value [a]			<.001			0.211
		Mean Diff (95% CI) [b]			4.2 (-0.2, 8.6)			
		P-value [b]			0.060			
		Effect Size (95% CI) [c]			0.18 (-0.03, 0.39)			
	C3D1	N	123	123	123	101	101	101
		Mean	73.3	81.4	8.1	73.4	78.0	4.5
		SD	24.65	20.61	21.43	22.10	22.32	19.20
		95% CI	68.9, 77.7	77.7, 85.1	4.2, 11.9	69.1, 77.8	73.6, 82.4	0.7, 8.3
		Median	83.3	83.3	8.3	83.3	83.3	0.0
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 16.7	66.7, 91.7	66.7, 100.0	-8.3, 16.7
		Min, Max	0.0, 100.0	8.3, 100.0	-41.7, 100.0	8.3, 100.0	8.3, 100.0	-41.7, 75.0
		Mean Diff (95% CI) [a]			8.1 (4.2, 11.9)			4.5 (0.7, 8.3)
		P-value [a]			<.001			0.019
		Mean Diff (95% CI) [b]			3.5 (-1.9, 8.9)			
		P-value [b]			0.201			
		Effect Size (95% CI) [c]			0.15 (-0.06, 0.36)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	73.0	80.6	7.5	73.2	78.7	5.4
		SD	23.91	21.98	21.49	22.09	23.93	21.86
		95% CI	68.5, 77.5	76.4, 84.7	3.5, 11.6	68.7, 77.8	73.8, 83.6	1.0, 9.9
		Median	75.0	83.3	8.3	83.3	83.3	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	-1.4, 16.7	66.7, 91.7	66.7, 100.0	-8.3, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-58.3, 91.7	8.3, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			7.5 (3.5, 11.6)			5.4 (1.0, 9.9)
		P-value [a]			<.001			0.018
		Mean Diff (95% CI) [b]			2.1 (-3.9, 8.1)			
		P-value [b]			0.488			
		Effect Size (95% CI) [c]			0.09 (-0.12, 0.30)			
	C5D1	N	98	98	98	80	80	80
		Mean	72.0	79.8	7.8	72.3	79.2	6.9
		SD	25.05	24.40	20.72	22.57	19.98	20.19
		95% CI	66.9, 77.0	74.9, 84.7	3.7, 12.0	67.3, 77.3	74.7, 83.6	2.4, 11.4
		Median	75.0	91.7	8.3	79.2	83.3	0.0
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 16.7	66.7, 91.7	66.7, 100.0	0.0, 8.3
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 91.7	8.3, 100.0	16.7, 100.0	-33.3, 66.7
		Mean Diff (95% CI) [a]			7.8 (3.7, 12.0)			6.9 (2.4, 11.4)
		P-value [a]			<.001			0.003
		Mean Diff (95% CI) [b]			0.9 (-5.1, 7.0)			
		P-value [b]			0.759			
		Effect Size (95% CI) [c]			0.04 (-0.17, 0.25)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	68	68	68
		Mean	73.4	81.8	8.4	74.0	82.2	8.2
		SD	23.64	22.70	21.16	21.43	18.38	19.24
		95% CI	68.6, 78.2	77.2, 86.4	4.1, 12.7	68.8, 79.2	77.8, 86.7	3.6, 12.9
		Median	79.2	91.7	8.3	79.2	83.3	4.2
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 20.8	66.7, 91.7	75.0, 100.0	0.0, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 58.3	8.3, 100.0	25.0, 100.0	-25.0, 83.3
		Mean Diff (95% CI) [a]			8.4 (4.1, 12.7)			8.2 (3.6, 12.9)
		P-value [a]			<.001			0.001
		Mean Diff (95% CI) [b]			0.2 (-6.2, 6.6)			
		P-value [b]			0.956			
		Effect Size (95% CI) [c]			0.01 (-0.20, 0.22)			
	C7D1	N	79	79	79	52	52	52
		Mean	72.8	82.4	9.6	73.6	84.1	10.6
		SD	25.72	22.50	20.50	23.09	19.26	19.18
		95% CI	67.1, 78.6	77.4, 87.5	5.0, 14.2	67.1, 80.0	78.8, 89.5	5.2, 15.9
		Median	83.3	91.7	8.3	83.3	91.7	8.3
		Q1, Q3	58.3, 91.7	75.0, 100.0	0.0, 25.0	66.7, 91.7	75.0, 100.0	0.0, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-75.0, 58.3	8.3, 100.0	16.7, 100.0	-16.7, 75.0
		Mean Diff (95% CI) [a]			9.6 (5.0, 14.2)			10.6 (5.2, 15.9)
		P-value [a]			<.001			<.001
		Mean Diff (95% CI) [b]			-1.0 (-8.0, 6.1)			
		P-value [b]			0.785			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.17)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	75	75	75	50	50	50
		Mean	73.6	81.9	8.3	73.5	82.7	9.2
		SD	25.01	22.94	23.97	23.55	24.27	22.29
		95% CI	67.8, 79.3	76.6, 87.2	2.8, 13.8	66.8, 80.2	75.8, 89.6	2.8, 15.5
		Median	83.3	91.7	0.0	83.3	91.7	8.3
		Q1, Q3	58.3, 91.7	75.0, 100.0	0.0, 25.0	66.7, 91.7	75.0, 100.0	0.0, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-83.3, 75.0	8.3, 100.0	0.0, 100.0	-41.7, 75.0
		Mean Diff (95% CI) [a]			8.3 (2.8, 13.8)			9.2 (2.8, 15.5)
		P-value [a]			0.004			0.005
		Mean Diff (95% CI) [b]			-0.8 (-9.3, 7.6)			
		P-value [b]			0.845			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.18)			
	C9D1	N	60	60	60	42	42	42
		Mean	72.5	84.2	11.7	72.8	83.9	11.1
		SD	23.38	19.75	22.87	24.28	20.19	21.44
		95% CI	66.5, 78.5	79.1, 89.3	5.8, 17.6	65.3, 80.4	77.6, 90.2	4.4, 17.8
		Median	75.0	91.7	8.3	83.3	91.7	8.3
		Q1, Q3	58.3, 91.7	75.0, 100.0	0.0, 25.0	66.7, 91.7	75.0, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	8.3, 100.0	-75.0, 58.3	8.3, 100.0	33.3, 100.0	-16.7, 91.7
		Mean Diff (95% CI) [a]			11.7 (5.8, 17.6)			11.1 (4.4, 17.8)
		P-value [a]			<.001			0.002
		Mean Diff (95% CI) [b]			0.6 (-8.3, 9.5)			
		P-value [b]			0.902			
		Effect Size (95% CI) [c]			0.02 (-0.19, 0.24)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	72.5	82.4	9.9	73.3	83.3	10.0
		SD	24.32	19.67	21.54	22.57	20.29	20.58
		95% CI	65.9, 79.2	77.0, 87.8	4.0, 15.8	64.9, 81.8	75.8, 90.9	2.3, 17.7
		Median	75.0	91.7	8.3	79.2	91.7	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 25.0	66.7, 91.7	66.7, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	8.3, 100.0	-75.0, 58.3	8.3, 100.0	33.3, 100.0	-50.0, 75.0
		Mean Diff (95% CI) [a]			9.9 (4.0, 15.8)			10.0 (2.3, 17.7)
		P-value [a]			0.001			0.013
		Mean Diff (95% CI) [b]			-0.1 (-9.7, 9.5)			
		P-value [b]			0.980			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.21)			
	C11D1	N	46	46	46	23	23	23
		Mean	70.1	77.7	7.6	73.2	87.3	14.1
		SD	24.06	21.73	23.56	23.56	17.20	22.25
		95% CI	63.0, 77.3	71.3, 84.2	0.6, 14.6	63.0, 83.4	79.9, 94.8	4.5, 23.8
		Median	66.7	79.2	8.3	75.0	100.0	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 16.7	66.7, 91.7	75.0, 100.0	0.0, 25.0
		Min, Max	16.7, 100.0	25.0, 100.0	-58.3, 58.3	8.3, 100.0	33.3, 100.0	-16.7, 83.3
		Mean Diff (95% CI) [a]			7.6 (0.6, 14.6)			14.1 (4.5, 23.8)
		P-value [a]			0.034			0.006
		Mean Diff (95% CI) [b]			-6.5 (-18.3, 5.3)			
		P-value [b]			0.274			
		Effect Size (95% CI) [c]			-0.28 (-0.49, -0.06)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	72.0	80.1	8.1	71.5	83.8	12.3
		SD	22.42	22.20	25.79	22.96	21.60	24.75
		95% CI	64.9, 79.0	73.1, 87.1	0.0, 16.3	60.4, 82.6	73.4, 94.2	0.4, 24.2
		Median	66.7	83.3	8.3	75.0	83.3	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 16.7	66.7, 83.3	75.0, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	8.3, 100.0	-75.0, 75.0	8.3, 91.7	8.3, 100.0	-33.3, 91.7
		Mean Diff (95% CI) [a]			8.1 (0.0, 16.3)			12.3 (0.4, 24.2)
		P-value [a]			0.050			0.044
		Mean Diff (95% CI) [b]			-4.2 (-18.3, 10.0)			
		P-value [b]			0.559			
		Effect Size (95% CI) [c]			-0.18 (-0.39, 0.04)			
	C13D1	N	33	33	33	15	15	15
		Mean	71.0	81.1	10.1	76.7	88.9	12.2
		SD	23.95	19.24	21.42	21.64	13.61	23.12
		95% CI	62.5, 79.5	74.2, 87.9	2.5, 17.7	64.7, 88.7	81.4, 96.4	-0.6, 25.0
		Median	66.7	83.3	8.3	83.3	100.0	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 16.7	66.7, 91.7	75.0, 100.0	0.0, 25.0
		Min, Max	16.7, 100.0	25.0, 100.0	-33.3, 75.0	8.3, 100.0	66.7, 100.0	-25.0, 75.0
		Mean Diff (95% CI) [a]			10.1 (2.5, 17.7)			12.2 (-0.6, 25.0)
		P-value [a]			0.011			0.060
		Mean Diff (95% CI) [b]			-2.1 (-15.9, 11.6)			
		P-value [b]			0.758			
		Effect Size (95% CI) [c]			-0.09 (-0.30, 0.12)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	73.0	83.8	10.9	75.0	88.2	13.2
		SD	22.73	19.43	19.93	23.03	13.04	22.04
		95% CI	64.9, 81.0	77.0, 90.7	3.8, 17.9	60.4, 89.6	79.9, 96.5	-0.8, 27.2
		Median	66.7	91.7	8.3	79.2	91.7	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 25.0	70.8, 91.7	75.0, 100.0	4.2, 16.7
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 50.0	8.3, 91.7	66.7, 100.0	-16.7, 75.0
		Mean Diff (95% CI) [a]			10.9 (3.8, 17.9)			13.2 (-0.8, 27.2)
		P-value [a]			0.004			0.062
		Mean Diff (95% CI) [b]			-2.3 (-16.3, 11.6)			
		P-value [b]			0.737			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.11)			
	C15D1	N	28	28	28	13	13	13
		Mean	70.8	79.2	8.3	74.4	85.3	10.9
		SD	23.30	23.73	21.64	22.17	14.50	27.51
		95% CI	61.8, 79.9	70.0, 88.4	-0.1, 16.7	61.0, 87.8	76.5, 94.0	-5.7, 27.5
		Median	66.7	83.3	8.3	75.0	83.3	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 25.0	66.7, 91.7	75.0, 100.0	0.0, 8.3
		Min, Max	16.7, 100.0	0.0, 100.0	-33.3, 50.0	8.3, 91.7	58.3, 100.0	-16.7, 91.7
		Mean Diff (95% CI) [a]			8.3 (-0.1, 16.7)			10.9 (-5.7, 27.5)
		P-value [a]			0.051			0.179
		Mean Diff (95% CI) [b]			-2.6 (-18.6, 13.5)			
		P-value [b]			0.748			
		Effect Size (95% CI) [c]			-0.11 (-0.32, 0.10)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	73.8	82.1	8.3	74.2	83.3	9.2
		SD	21.84	20.63	21.52	25.29	14.70	25.29
		95% CI	65.3, 82.3	74.1, 90.1	0.0, 16.7	56.1, 92.3	72.8, 93.8	-8.9, 27.3
		Median	70.8	91.7	8.3	79.2	83.3	8.3
		Q1, Q3	62.5, 91.7	66.7, 100.0	0.0, 20.8	66.7, 91.7	75.0, 100.0	0.0, 8.3
		Min, Max	16.7, 100.0	33.3, 100.0	-41.7, 41.7	8.3, 91.7	58.3, 100.0	-16.7, 75.0
		Mean Diff (95% CI) [a]			8.3 (0.0, 16.7)			9.2 (-8.9, 27.3)
		P-value [a]			0.050			0.281
		Mean Diff (95% CI) [b]			-0.8 (-17.7, 16.0)			
		P-value [b]			0.921			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.18)			
	C17D1	N	26	26	26	7	7	7
		Mean	72.1	80.8	8.7	71.4	92.9	21.4
		SD	21.72	22.46	19.36	29.60	8.91	33.28
		95% CI	63.3, 80.9	71.7, 89.8	0.8, 16.5	44.1, 98.8	84.6, 101.1	-9.4, 52.2
		Median	66.7	91.7	8.3	75.0	100.0	8.3
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 16.7	66.7, 91.7	83.3, 100.0	8.3, 33.3
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 41.7	8.3, 91.7	83.3, 100.0	-8.3, 91.7
		Mean Diff (95% CI) [a]			8.7 (0.8, 16.5)			21.4 (-9.4, 52.2)
		P-value [a]			0.031			0.139
		Mean Diff (95% CI) [b]			-12.8 (-32.5, 7.0)			
		P-value [b]			0.197			
		Effect Size (95% CI) [c]			-0.54 (-0.76, -0.32)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	69.3	82.6	13.3	71.4	91.7	20.2
		SD	21.73	19.40	19.36	29.60	14.43	33.97
		95% CI	59.7, 79.0	74.0, 91.2	4.7, 21.8	44.1, 98.8	78.3, 105.0	-11.2, 51.7
		Median	66.7	87.5	16.7	75.0	100.0	8.3
		Q1, Q3	58.3, 83.3	66.7, 100.0	0.0, 25.0	66.7, 91.7	75.0, 100.0	0.0, 33.3
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 50.0	8.3, 91.7	66.7, 100.0	-8.3, 91.7
		Mean Diff (95% CI) [a]			13.3 (4.7, 21.8)			20.2 (-11.2, 51.7)
		P-value [a]			0.004			0.166
		Mean Diff (95% CI) [b]			-7.0 (-27.8, 13.9)			
		P-value [b]			0.498			
		Effect Size (95% CI) [c]			-0.30 (-0.51, -0.08)			
	C19D1	N	20	20	20	6	6	6
		Mean	70.0	82.1	12.1	68.1	81.9	13.9
		SD	22.36	18.39	20.85	30.92	17.81	29.66
		95% CI	59.5, 80.5	73.5, 90.7	2.3, 21.8	35.6, 100.5	63.3, 100.6	-17.2, 45.0
		Median	66.7	87.5	16.7	75.0	83.3	8.3
		Q1, Q3	58.3, 87.5	66.7, 100.0	0.0, 29.2	66.7, 91.7	66.7, 100.0	-8.3, 25.0
		Min, Max	16.7, 100.0	50.0, 100.0	-33.3, 41.7	8.3, 91.7	58.3, 100.0	-16.7, 66.7
		Mean Diff (95% CI) [a]			12.1 (2.3, 21.8)			13.9 (-17.2, 45.0)
		P-value [a]			0.018			0.303
		Mean Diff (95% CI) [b]			-1.8 (-23.9, 20.3)			
		P-value [b]			0.867			
		Effect Size (95% CI) [c]			-0.08 (-0.29, 0.14)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	19	19	19	4	4	4
		Mean	71.1	82.0	11.0	77.1	91.7	14.6
		SD	23.14	23.78	21.53	10.49	11.79	14.23
		95% CI	59.9, 82.2	70.6, 93.5	0.6, 21.3	60.4, 93.8	72.9, 110.4	-8.1, 37.2
		Median	66.7	91.7	16.7	75.0	95.8	12.5
		Q1, Q3	58.3, 91.7	66.7, 100.0	0.0, 25.0	70.8, 83.3	83.3, 100.0	4.2, 25.0
		Min, Max	16.7, 100.0	16.7, 100.0	-33.3, 41.7	66.7, 91.7	75.0, 100.0	0.0, 33.3
		Mean Diff (95% CI) [a]			11.0 (0.6, 21.3)			14.6 (-8.1, 37.2)
		P-value [a]			0.039			0.133
		Mean Diff (95% CI) [b]			-3.6 (-27.2, 20.0)			
		P-value [b]			0.753			
		Effect Size (95% CI) [c]			-0.15 (-0.37, 0.06)			
	C21D1	N	18	18	18	4	4	4
		Mean	69.0	81.0	12.0	77.1	85.4	8.3
		SD	22.29	17.57	20.05	10.49	17.18	11.79
		95% CI	57.9, 80.1	72.3, 89.8	2.1, 22.0	60.4, 93.8	58.1, 112.8	-10.4, 27.1
		Median	66.7	83.3	16.7	75.0	87.5	4.2
		Q1, Q3	58.3, 83.3	66.7, 100.0	0.0, 25.0	70.8, 83.3	70.8, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 41.7	66.7, 91.7	66.7, 100.0	0.0, 25.0
		Mean Diff (95% CI) [a]			12.0 (2.1, 22.0)			8.3 (-10.4, 27.1)
		P-value [a]			0.021			0.252
		Mean Diff (95% CI) [b]			3.7 (-18.3, 25.7)			
		P-value [b]			0.729			
		Effect Size (95% CI) [c]			0.16 (-0.06, 0.37)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	72.8	80.0	7.2	77.8	88.9	11.1
		SD	24.29	17.76	18.86	12.73	19.25	12.73
		95% CI	59.3, 86.2	70.2, 89.8	-3.2, 17.7	46.2, 109.4	41.1, 136.7	-20.5, 42.7
		Median	83.3	83.3	8.3	75.0	100.0	8.3
		Q1, Q3	66.7, 91.7	66.7, 91.7	0.0, 16.7	66.7, 91.7	66.7, 100.0	0.0, 25.0
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 41.7	66.7, 91.7	66.7, 100.0	0.0, 25.0
		Mean Diff (95% CI) [a]			7.2 (-3.2, 17.7)			11.1 (-20.5, 42.7)
		P-value [a]			0.160			0.270
		Mean Diff (95% CI) [b]			-3.9 (-28.3, 20.5)			
		P-value [b]			0.740			
		Effect Size (95% CI) [c]			-0.16 (-0.38, 0.05)			
	C23D1	N	11	11	11	3	3	3
		Mean	74.2	78.8	4.5	77.8	91.7	13.9
		SD	24.85	17.23	22.47	12.73	14.43	9.62
		95% CI	57.5, 90.9	67.2, 90.4	-10.6, 19.6	46.2, 109.4	55.8, 127.5	-10.0, 37.8
		Median	83.3	83.3	16.7	75.0	100.0	8.3
		Q1, Q3	66.7, 91.7	66.7, 91.7	-8.3, 16.7	66.7, 91.7	75.0, 100.0	8.3, 25.0
		Min, Max	16.7, 100.0	41.7, 100.0	-33.3, 33.3	66.7, 91.7	75.0, 100.0	8.3, 25.0
		Mean Diff (95% CI) [a]			4.5 (-10.6, 19.6)			13.9 (-10.0, 37.8)
		P-value [a]			0.518			0.130
		Mean Diff (95% CI) [b]			-9.3 (-39.0, 20.3)			
		P-value [b]			0.505			
		Effect Size (95% CI) [c]			-0.40 (-0.61, -0.18)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	76.7	84.2	7.5	70.8	70.8	0.0
		SD	24.78	23.39	17.32	5.89	5.89	0.00
		95% CI	58.9, 94.4	67.4, 100.9	-4.9, 19.9	17.9, 123.8	17.9, 123.8	0.0, 0.0
		Median	83.3	91.7	8.3	70.8	70.8	0.0
		Q1, Q3	66.7, 91.7	83.3, 100.0	0.0, 16.7	66.7, 75.0	66.7, 75.0	0.0, 0.0
		Min, Max	16.7, 100.0	25.0, 100.0	-33.3, 33.3	66.7, 75.0	66.7, 75.0	0.0, 0.0
		Mean Diff (95% CI) [a]			7.5 (-4.9, 19.9)			0.0 (0.0, 0.0)
		P-value [a]			0.204			NE
		Mean Diff (95% CI) [b]			7.5 (-20.9, 35.9)			
		P-value [b]			0.569			
		Effect Size (95% CI) [c]			0.32 (0.10, 0.53)			
	C25D1	N	9	9	9	0	0	0
		Mean	75.0	78.7	3.7	NE	NE	NE
		SD	25.69	26.39	22.09	NE	NE	NE
		95% CI	55.3, 94.7	58.4, 99.0	-13.3, 20.7	NE, NE	NE, NE	NE, NE
		Median	83.3	83.3	8.3	NE	NE	NE
		Q1, Q3	66.7, 91.7	75.0, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	16.7, 100.0	16.7, 100.0	-33.3, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			3.7 (-13.3, 20.7)			NE (NE, NE)
		P-value [a]			0.629			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	83.3	84.4	1.0	75.0	100.0	25.0
		SD	14.77	23.33	32.56	NE	NE	NE
		95% CI	71.0, 95.7	64.9, 103.9	-26.2, 28.3	NE, NE	NE, NE	NE, NE
		Median	87.5	95.8	8.3	75.0	100.0	25.0
		Q1, Q3	66.7, 95.8	75.0, 100.0	-12.5, 25.0	75.0, 75.0	100.0, 100.0	25.0, 25.0
		Min, Max	66.7, 100.0	33.3, 100.0	-66.7, 33.3	75.0, 75.0	100.0, 100.0	25.0, 25.0
		Mean Diff (95% CI) [a]			1.0 (-26.2, 28.3)			25.0 (NE, NE)
		P-value [a]			0.930			NE
		Mean Diff (95% CI) [b]			-24.0 (-105.6, 57.7)			
		P-value [b]			0.510			
		Effect Size (95% CI) [c]			-1.02 (-1.24, -0.79)			
	C27D1	N	8	8	8	1	1	1
		Mean	83.3	83.3	0.0	75.0	91.7	16.7
		SD	14.77	12.60	19.92	NE	NE	NE
		95% CI	71.0, 95.7	72.8, 93.9	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Median	87.5	79.2	8.3	75.0	91.7	16.7
		Q1, Q3	66.7, 95.8	75.0, 95.8	-16.7, 12.5	75.0, 75.0	91.7, 91.7	16.7, 16.7
		Min, Max	66.7, 100.0	66.7, 100.0	-33.3, 25.0	75.0, 75.0	91.7, 91.7	16.7, 16.7
		Mean Diff (95% CI) [a]			0.0 (-16.7, 16.7)			16.7 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			-16.7 (-66.6, 33.3)			
		P-value [b]			0.456			
		Effect Size (95% CI) [c]			-0.71 (-0.93, -0.49)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	85.7	84.5	-1.2	75.0	100.0	25.0
		SD	14.20	12.20	20.65	NE	NE	NE
		95% CI	72.6, 98.8	73.2, 95.8	-20.3, 17.9	NE, NE	NE, NE	NE, NE
		Median	91.7	83.3	8.3	75.0	100.0	25.0
		Q1, Q3	66.7, 100.0	75.0, 100.0	-16.7, 16.7	75.0, 75.0	100.0, 100.0	25.0, 25.0
		Min, Max	66.7, 100.0	66.7, 100.0	-33.3, 16.7	75.0, 75.0	100.0, 100.0	25.0, 25.0
		Mean Diff (95% CI) [a]			-1.2 (-20.3, 17.9)			25.0 (NE, NE)
		P-value [a]			0.884			NE
		Mean Diff (95% CI) [b]			-26.2 (-80.2, 27.8)			
		P-value [b]			0.280			
		Effect Size (95% CI) [c]			-1.11 (-1.34, -0.88)			
	C29D1	N	4	4	4	1	1	1
		Mean	85.4	75.0	-10.4	75.0	66.7	-8.3
		SD	14.23	18.00	26.68	NE	NE	NE
		95% CI	62.8, 108.1	46.4, 103.6	-52.9, 32.0	NE, NE	NE, NE	NE, NE
		Median	87.5	70.8	-12.5	75.0	66.7	-8.3
		Q1, Q3	75.0, 95.8	62.5, 87.5	-33.3, 12.5	75.0, 75.0	66.7, 66.7	-8.3, -8.3
		Min, Max	66.7, 100.0	58.3, 100.0	-33.3, 16.7	75.0, 75.0	66.7, 66.7	-8.3, -8.3
		Mean Diff (95% CI) [a]			-10.4 (-52.9, 32.0)			-8.3 (NE, NE)
		P-value [a]			0.492			NE
		Mean Diff (95% CI) [b]			-2.1 (-97.0, 92.8)			
		P-value [b]			0.949			
		Effect Size (95% CI) [c]			-0.09 (-0.30, 0.12)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	83.3	85.4	2.1	75.0	33.3	-41.7
		SD	11.79	17.18	18.48	NE	NE	NE
		95% CI	64.6, 102.1	58.1, 112.8	-27.3, 31.5	NE, NE	NE, NE	NE, NE
		Median	87.5	87.5	8.3	75.0	33.3	-41.7
		Q1, Q3	75.0, 91.7	70.8, 100.0	-8.3, 12.5	75.0, 75.0	33.3, 33.3	-41.7, -41.7
		Min, Max	66.7, 91.7	66.7, 100.0	-25.0, 16.7	75.0, 75.0	33.3, 33.3	-41.7, -41.7
		Mean Diff (95% CI) [a]			2.1 (-27.3, 31.5)			-41.7 (NE, NE)
		P-value [a]			0.836			NE
		Mean Diff (95% CI) [b]			43.8 (-22.0, 109.5)			
		P-value [b]			0.124			
		Effect Size (95% CI) [c]			1.85 (1.60, 2.11)			
	C31D1	N	2	2	2	1	1	1
		Mean	75.0	87.5	12.5	75.0	66.7	-8.3
		SD	11.79	17.68	5.89	NE	NE	NE
		95% CI	-30.9, 180.9	-71.3, 246.3	-40.4, 65.4	NE, NE	NE, NE	NE, NE
		Median	75.0	87.5	12.5	75.0	66.7	-8.3
		Q1, Q3	66.7, 83.3	75.0, 100.0	8.3, 16.7	75.0, 75.0	66.7, 66.7	-8.3, -8.3
		Min, Max	66.7, 83.3	75.0, 100.0	8.3, 16.7	75.0, 75.0	66.7, 66.7	-8.3, -8.3
		Mean Diff (95% CI) [a]			12.5 (-40.4, 65.4)			-8.3 (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			20.8 (-70.9, 112.5)			
		P-value [b]			0.212			
		Effect Size (95% CI) [c]			0.88 (0.66, 1.11)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	75.0	87.5	12.5	75.0	75.0	0.0
		SD	11.79	17.68	5.89	NE	NE	NE
		95% CI	-30.9, 180.9	-71.3, 246.3	-40.4, 65.4	NE, NE	NE, NE	NE, NE
		Median	75.0	87.5	12.5	75.0	75.0	0.0
		Q1, Q3	66.7, 83.3	75.0, 100.0	8.3, 16.7	75.0, 75.0	75.0, 75.0	0.0, 0.0
		Min, Max	66.7, 83.3	75.0, 100.0	8.3, 16.7	75.0, 75.0	75.0, 75.0	0.0, 0.0
		Mean Diff (95% CI) [a]			12.5 (-40.4, 65.4)			0.0 (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			12.5 (-79.2, 104.2)			
		P-value [b]			0.333			
		Effect Size (95% CI) [c]			0.53 (0.31, 0.75)			
	C33D1	N	3	3	3	1	1	1
		Mean	80.6	91.7	11.1	75.0	75.0	0.0
		SD	12.73	14.43	4.81	NE	NE	NE
		95% CI	48.9, 112.2	55.8, 127.5	-0.8, 23.1	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	8.3	75.0	75.0	0.0
		Q1, Q3	66.7, 91.7	75.0, 100.0	8.3, 16.7	75.0, 75.0	75.0, 75.0	0.0, 0.0
		Min, Max	66.7, 91.7	75.0, 100.0	8.3, 16.7	75.0, 75.0	75.0, 75.0	0.0, 0.0
		Mean Diff (95% CI) [a]			11.1 (-0.8, 23.1)			0.0 (NE, NE)
		P-value [a]			0.057			NE
		Mean Diff (95% CI) [b]			11.1 (-12.8, 35.0)			
		P-value [b]			0.184			
		Effect Size (95% CI) [c]			0.47 (0.26, 0.69)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	80.6	88.9	8.3	NE	NE	NE
		SD	12.73	19.25	8.33	NE	NE	NE
		95% CI	48.9, 112.2	41.1, 136.7	-12.4, 29.0	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	8.3	NE	NE	NE
		Q1, Q3	66.7, 91.7	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 91.7	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-12.4, 29.0)			NE (NE, NE)
		P-value [a]			0.225			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	75.0	83.3	8.3	NE	NE	NE
		SD	11.79	23.57	11.79	NE	NE	NE
		95% CI	-30.9, 180.9	-128.4, 295.1	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Median	75.0	83.3	8.3	NE	NE	NE
		Q1, Q3	66.7, 83.3	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 83.3	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	80.6	88.9	8.3	NE	NE	NE
		SD	12.73	19.25	8.33	NE	NE	NE
		95% CI	48.9, 112.2	41.1, 136.7	-12.4, 29.0	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	8.3	NE	NE	NE
		Q1, Q3	66.7, 91.7	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 91.7	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-12.4, 29.0)			NE (NE, NE)
		P-value [a]			0.225			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	80.6	88.9	8.3	NE	NE	NE
		SD	12.73	19.25	8.33	NE	NE	NE
		95% CI	48.9, 112.2	41.1, 136.7	-12.4, 29.0	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	8.3	NE	NE	NE
		Q1, Q3	66.7, 91.7	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 91.7	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-12.4, 29.0)			NE (NE, NE)
		P-value [a]			0.225			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	87.5	100.0	12.5	NE	NE	NE
		SD	5.89	0.00	5.89	NE	NE	NE
		Median	87.5	100.0	12.5	NE	NE	NE
		95% CI	34.6, 140.4	100.0, 100.0	-40.4, 65.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			12.5 (-40.4, 65.4)			NE (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	87.5	100.0	12.5	NE	NE	NE
		SD	5.89	0.00	5.89	NE	NE	NE
		95% CI	34.6, 140.4	100.0, 100.0	-40.4, 65.4	NE, NE	NE, NE	NE, NE
		Median	87.5	100.0	12.5	NE	NE	NE
		Q1, Q3	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			12.5 (-40.4, 65.4)			NE (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	87.5	100.0	12.5	NE	NE	NE
		SD	5.89	0.00	5.89	NE	NE	NE
		95% CI	34.6, 140.4	100.0, 100.0	-40.4, 65.4	NE, NE	NE, NE	NE, NE
		Median	87.5	100.0	12.5	NE	NE	NE
		Q1, Q3	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			12.5 (-40.4, 65.4)			NE (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	87.5	100.0	12.5	NE	NE	NE
		SD	5.89	0.00	5.89	NE	NE	NE
		95% CI	34.6, 140.4	100.0, 100.0	-40.4, 65.4	NE, NE	NE, NE	NE, NE
		Median	87.5	100.0	12.5	NE	NE	NE
		Q1, Q3	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 91.7	100.0, 100.0	8.3, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			12.5 (-40.4, 65.4)			NE (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	16.7	NE	NE	NE
		Q1, Q3	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	16.7	NE	NE	NE
		Q1, Q3	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	130	130	130	125	125	125
		Mean	70.0	72.4	2.4	74.5	73.1	-1.3
		SD	26.63	25.59	24.23	21.50	21.11	20.29
		95% CI	65.4, 74.6	68.0, 76.8	-1.8, 6.6	70.7, 78.3	69.4, 76.9	-4.9, 2.3
		Median	75.0	75.0	0.0	83.3	75.0	0.0
		Q1, Q3	58.3, 91.7	58.3, 91.7	-8.3, 8.3	66.7, 91.7	58.3, 91.7	-16.7, 8.3
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 91.7	8.3, 100.0	0.0, 100.0	-58.3, 75.0
		Mean Diff (95% CI) [a]			2.4 (-1.8, 6.6)			-1.3 (-4.9, 2.3)
		P-value [a]			0.262			0.464
		Mean Diff (95% CI) [b]			3.7 (-1.8, 9.2)			
		P-value [b]			0.185			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	85.7	78.0	-7.7	75.9	60.2	-15.7
		SD	15.48	18.08	18.04	15.28	36.51	34.97
		95% CI	76.8, 94.7	67.5, 88.4	-18.2, 2.7	64.2, 87.7	32.1, 88.2	-42.6, 11.1
		Median	91.7	75.0	-4.2	66.7	66.7	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-25.0, 0.0	66.7, 83.3	41.7, 83.3	-33.3, 0.0
		Min, Max	66.7, 100.0	41.7, 100.0	-33.3, 33.3	58.3, 100.0	0.0, 100.0	-83.3, 33.3
		Mean Diff (95% CI) [a]			-7.7 (-18.2, 2.7)			-15.7 (-42.6, 11.1)
		P-value [a]			0.133			0.214
		Mean Diff (95% CI) [b]			8.0 (-15.0, 31.0)			
		P-value [b]			0.476			
		Effect Size (95% CI) [c]			0.34 (0.13, 0.55)			
Cognitive Functioning	Baseline	N	174			165		
		Mean	85.5			83.9		
		SD	19.79			20.81		
		95% CI	82.6, 88.5			80.7, 87.1		
		Median	100.0			83.3		
		Q1, Q3	83.3, 100.0			66.7, 100.0		
		Min, Max	16.7, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	85.2	84.3	-0.9	83.7	83.1	-0.6
		SD	20.26	21.81	13.80	21.09	20.39	18.22
		Median	100.0	100.0	0.0	83.3	83.3	0.0
		95% CI	82.0, 88.4	80.8, 87.8	-3.1, 1.3	80.2, 87.2	79.7, 86.5	-3.6, 2.4
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-50.0, 50.0	0.0, 100.0	16.7, 100.0	-83.3, 66.7
		Mean Diff (95% CI) [a]			-0.9 (-3.1, 1.3)			-0.6 (-3.6, 2.4)
		P-value [a]			0.435			0.704
		Mean Diff (95% CI) [b]			-0.3 (-4.0, 3.4)			
		P-value [b]			0.873			
		Effect Size (95% CI) [c]			-0.01 (-0.23, 0.20)			
	C3D1	N	123	123	123	101	101	101
		Mean	86.0	87.5	1.5	84.0	83.8	-0.2
		SD	17.90	18.06	13.33	20.94	20.88	16.24
		Median	83.3	100.0	0.0	83.3	83.3	0.0
		95% CI	82.8, 89.2	84.3, 90.8	-0.9, 3.9	79.9, 88.1	79.7, 87.9	-3.4, 3.0
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	83.3, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-33.3, 50.0	0.0, 100.0	0.0, 100.0	-33.3, 83.3
		Mean Diff (95% CI) [a]			1.5 (-0.9, 3.9)			-0.2 (-3.4, 3.0)
		P-value [a]			0.217			0.919
		Mean Diff (95% CI) [b]			1.7 (-2.2, 5.5)			
		P-value [b]			0.403			
		Effect Size (95% CI) [c]			0.08 (-0.13, 0.29)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	85.4	85.6	0.1	84.2	84.6	0.4
		SD	18.47	21.98	15.74	21.50	20.48	17.45
		Median	83.3	100.0	0.0	91.7	83.3	0.0
		95% CI	82.0, 88.9	81.5, 89.7	-2.8, 3.1	79.8, 88.6	80.4, 88.8	-3.2, 3.9
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	83.3, 100.0	83.3, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	16.7, 100.0	-33.3, 83.3
		Mean Diff (95% CI) [a]			0.1 (-2.8, 3.1)			0.4 (-3.2, 3.9)
		P-value [a]			0.920			0.844
		Mean Diff (95% CI) [b]			-0.2 (-4.8, 4.4)			
		P-value [b]			0.929			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.20)			
	C5D1	N	98	98	98	80	80	80
		Mean	87.1	86.1	-1.0	83.5	84.0	0.4
		SD	16.50	20.26	15.29	21.95	21.12	16.56
		Median	83.3	100.0	0.0	83.3	83.3	0.0
		95% CI	83.8, 90.4	82.0, 90.1	-4.1, 2.0	78.7, 88.4	79.3, 88.7	-3.3, 4.1
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	75.0, 100.0	83.3, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 33.3	0.0, 100.0	16.7, 100.0	-50.0, 83.3
		Mean Diff (95% CI) [a]			-1.0 (-4.1, 2.0)			0.4 (-3.3, 4.1)
		P-value [a]			0.510			0.822
		Mean Diff (95% CI) [b]			-1.4 (-6.2, 3.3)			
		P-value [b]			0.549			
		Effect Size (95% CI) [c]			-0.07 (-0.28, 0.14)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	68	68	68
		Mean	85.9	88.7	2.8	83.3	82.8	-0.5
		SD	17.49	15.58	14.03	21.16	21.15	12.54
		Median	83.3	100.0	0.0	91.7	83.3	0.0
		95% CI	82.4, 89.5	85.6, 91.9	-0.1, 5.6	78.2, 88.5	77.7, 88.0	-3.5, 2.5
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	33.3, 100.0	-33.3, 66.7	33.3, 100.0	33.3, 100.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			2.8 (-0.1, 5.6)			-0.5 (-3.5, 2.5)
		P-value [a]			0.055			0.748
		Mean Diff (95% CI) [b]			3.3 (-0.9, 7.5)			
		P-value [b]			0.127			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			
	C7D1	N	79	79	79	52	52	52
		Mean	85.7	86.3	0.6	83.7	84.0	0.3
		SD	18.82	22.13	16.33	21.00	20.86	14.57
		Median	83.3	100.0	0.0	83.3	100.0	0.0
		95% CI	81.4, 89.9	81.3, 91.2	-3.0, 4.3	77.8, 89.5	78.2, 89.8	-3.7, 4.4
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 16.7	75.0, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	16.7, 100.0	-50.0, 33.3	33.3, 100.0	33.3, 100.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			0.6 (-3.0, 4.3)			0.3 (-3.7, 4.4)
		P-value [a]			0.731			0.875
		Mean Diff (95% CI) [b]			0.3 (-5.2, 5.8)			
		P-value [b]			0.911			
		Effect Size (95% CI) [c]			0.02 (-0.20, 0.23)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	75	75	75	50	50	50
		Mean	85.6	86.0	0.4	81.7	85.0	3.3
		SD	19.25	20.33	16.43	20.82	21.63	15.06
		Median	83.3	100.0	0.0	83.3	100.0	0.0
		95% CI	81.1, 90.0	81.3, 90.7	-3.3, 4.2	75.7, 87.6	78.9, 91.1	-0.9, 7.6
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	16.7, 100.0	-50.0, 66.7	33.3, 100.0	0.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			0.4 (-3.3, 4.2)			3.3 (-0.9, 7.6)
		P-value [a]			0.815			0.124
		Mean Diff (95% CI) [b]			-2.9 (-8.6, 2.9)			
		P-value [b]			0.322			
		Effect Size (95% CI) [c]			-0.14 (-0.35, 0.07)			
	C9D1	N	60	60	60	42	42	42
		Mean	87.5	86.9	-0.6	82.5	84.1	1.6
		SD	16.70	18.94	18.15	20.81	19.11	15.53
		Median	91.7	100.0	0.0	83.3	83.3	0.0
		95% CI	83.2, 91.8	82.1, 91.8	-5.2, 4.1	76.1, 89.0	78.2, 90.1	-3.3, 6.4
		Q1, Q3	83.3, 100.0	75.0, 100.0	0.0, 0.0	66.7, 100.0	66.7, 100.0	0.0, 0.0
		Min, Max	16.7, 100.0	33.3, 100.0	-50.0, 66.7	33.3, 100.0	33.3, 100.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			-0.6 (-5.2, 4.1)			1.6 (-3.3, 6.4)
		P-value [a]			0.813			0.512
		Mean Diff (95% CI) [b]			-2.1 (-9.0, 4.7)			
		P-value [b]			0.535			
		Effect Size (95% CI) [c]			-0.11 (-0.32, 0.11)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	86.4	85.5	-0.9	81.1	83.3	2.2
		SD	18.34	22.21	21.09	22.63	22.74	14.99
		Median	91.7	100.0	0.0	83.3	100.0	0.0
		95% CI	81.4, 91.4	79.4, 91.6	-6.7, 4.8	72.7, 89.6	74.8, 91.8	-3.4, 7.8
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	0.0, 100.0	-83.3, 50.0	33.3, 100.0	33.3, 100.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			-0.9 (-6.7, 4.8)			2.2 (-3.4, 7.8)
		P-value [a]			0.748			0.423
		Mean Diff (95% CI) [b]			-3.1 (-11.8, 5.5)			
		P-value [b]			0.472			
		Effect Size (95% CI) [c]			-0.15 (-0.37, 0.06)			
	C11D1	N	46	46	46	23	23	23
		Mean	85.1	85.5	0.4	83.3	86.2	2.9
		SD	19.00	21.26	19.72	19.46	17.87	13.90
		Median	83.3	100.0	0.0	83.3	100.0	0.0
		95% CI	79.5, 90.8	79.2, 91.8	-5.5, 6.2	74.9, 91.7	78.5, 94.0	-3.1, 8.9
		Q1, Q3	83.3, 100.0	66.7, 100.0	0.0, 0.0	83.3, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	16.7, 100.0	0.0, 100.0	-83.3, 50.0	33.3, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			0.4 (-5.5, 6.2)			2.9 (-3.1, 8.9)
		P-value [a]			0.901			0.328
		Mean Diff (95% CI) [b]			-2.5 (-11.7, 6.6)			
		P-value [b]			0.583			
		Effect Size (95% CI) [c]			-0.12 (-0.34, 0.09)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	88.2	85.8	-2.4	83.3	86.8	3.5
		SD	14.55	21.59	15.17	17.57	22.62	16.27
		Median	83.3	100.0	0.0	83.3	100.0	0.0
		95% CI	83.6, 92.8	79.0, 92.6	-7.2, 2.3	74.9, 91.8	75.9, 97.7	-4.3, 11.4
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 100.0	83.3, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	16.7, 100.0	-50.0, 16.7	33.3, 100.0	16.7, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-2.4 (-7.2, 2.3)			3.5 (-4.3, 11.4)
		P-value [a]			0.309			0.360
		Mean Diff (95% CI) [b]			-5.9 (-14.6, 2.7)			
		P-value [b]			0.173			
		Effect Size (95% CI) [c]			-0.29 (-0.51, -0.08)			
	C13D1	N	33	33	33	15	15	15
		Mean	89.4	88.9	-0.5	81.1	84.4	3.3
		SD	14.92	18.00	11.40	17.67	21.33	15.69
		Median	100.0	100.0	0.0	83.3	100.0	0.0
		95% CI	84.1, 94.7	82.5, 95.3	-4.5, 3.5	71.3, 90.9	72.6, 96.3	-5.4, 12.0
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	-33.3, 16.7	33.3, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-0.5 (-4.5, 3.5)			3.3 (-5.4, 12.0)
		P-value [a]			0.801			0.424
		Mean Diff (95% CI) [b]			-3.8 (-11.9, 4.2)			
		P-value [b]			0.343			
		Effect Size (95% CI) [c]			-0.19 (-0.40, 0.02)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	88.4	90.4	2.0	80.6	83.3	2.8
		SD	15.30	16.68	9.09	18.58	26.59	18.58
		Median	100.0	100.0	0.0	83.3	100.0	0.0
		95% CI	83.0, 93.8	84.5, 96.3	-1.2, 5.2	68.8, 92.4	66.4, 100.2	-9.0, 14.6
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	75.0, 91.7	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	-16.7, 16.7	33.3, 100.0	33.3, 100.0	-50.0, 16.7
		Mean Diff (95% CI) [a]			2.0 (-1.2, 5.2)			2.8 (-9.0, 14.6)
		P-value [a]			0.211			0.615
		Mean Diff (95% CI) [b]			-0.8 (-9.1, 7.6)			
		P-value [b]			0.855			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.18)			
	C15D1	N	28	28	28	13	13	13
		Mean	88.1	85.7	-2.4	79.5	80.8	1.3
		SD	16.27	20.14	17.40	18.20	23.42	14.37
		Median	100.0	100.0	0.0	83.3	83.3	0.0
		95% CI	81.8, 94.4	77.9, 93.5	-9.1, 4.4	68.5, 90.5	66.6, 94.9	-7.4, 10.0
		Q1, Q3	83.3, 100.0	75.0, 100.0	0.0, 0.0	66.7, 83.3	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	16.7, 100.0	-50.0, 33.3	33.3, 100.0	33.3, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			-2.4 (-9.1, 4.4)			1.3 (-7.4, 10.0)
		P-value [a]			0.475			0.753
		Mean Diff (95% CI) [b]			-3.7 (-14.9, 7.6)			
		P-value [b]			0.513			
		Effect Size (95% CI) [c]			-0.18 (-0.39, 0.03)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	88.7	91.1	2.4	76.7	75.0	-1.7
		SD	15.75	17.26	10.84	19.56	25.15	16.57
		Median	100.0	100.0	0.0	83.3	75.0	0.0
		95% CI	82.6, 94.8	84.4, 97.8	-1.8, 6.6	62.7, 90.7	57.0, 93.0	-13.5, 10.2
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 8.3	66.7, 83.3	50.0, 100.0	-16.7, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	-33.3, 16.7	33.3, 100.0	33.3, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			2.4 (-1.8, 6.6)			-1.7 (-13.5, 10.2)
		P-value [a]			0.255			0.758
		Mean Diff (95% CI) [b]			4.0 (-5.3, 13.4)			
		P-value [b]			0.386			
		Effect Size (95% CI) [c]			0.20 (-0.01, 0.41)			
	C17D1	N	26	26	26	7	7	7
		Mean	88.5	90.4	1.9	71.4	69.0	-2.4
		SD	16.17	14.28	8.60	18.54	26.23	17.82
		Median	100.0	100.0	0.0	83.3	66.7	0.0
		95% CI	81.9, 95.0	84.6, 96.2	-1.5, 5.4	54.3, 88.6	44.8, 93.3	-18.9, 14.1
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 83.3	50.0, 100.0	-16.7, 16.7
		Min, Max	33.3, 100.0	50.0, 100.0	-16.7, 16.7	33.3, 83.3	33.3, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			1.9 (-1.5, 5.4)			-2.4 (-18.9, 14.1)
		P-value [a]			0.265			0.736
		Mean Diff (95% CI) [b]			4.3 (-5.3, 13.9)			
		P-value [b]			0.365			
		Effect Size (95% CI) [c]			0.21 (0.00, 0.42)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	88.6	88.6	0.0	73.8	66.7	-7.1
		SD	16.58	13.98	12.60	21.21	31.91	21.21
		Median	100.0	100.0	0.0	83.3	66.7	0.0
		95% CI	81.3, 96.0	82.4, 94.8	-5.6, 5.6	54.2, 93.4	37.2, 96.2	-26.8, 12.5
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 83.3	33.3, 100.0	-16.7, 0.0
		Min, Max	33.3, 100.0	66.7, 100.0	-33.3, 33.3	33.3, 100.0	16.7, 100.0	-50.0, 16.7
		Mean Diff (95% CI) [a]			0.0 (-5.6, 5.6)			-7.1 (-26.8, 12.5)
		P-value [a]			1.000			0.407
		Mean Diff (95% CI) [b]			7.1 (-6.2, 20.5)			
		P-value [b]			0.281			
		Effect Size (95% CI) [c]			0.35 (0.14, 0.57)			
	C19D1	N	20	20	20	6	6	6
		Mean	88.3	89.2	0.8	75.0	66.7	-8.3
		SD	17.18	13.55	12.65	22.97	27.89	20.41
		Median	100.0	100.0	0.0	83.3	58.3	0.0
		95% CI	80.3, 96.4	82.8, 95.5	-5.1, 6.8	50.9, 99.1	37.4, 95.9	-29.8, 13.1
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	66.7, 83.3	50.0, 100.0	-33.3, 0.0
		Min, Max	33.3, 100.0	66.7, 100.0	-33.3, 33.3	33.3, 100.0	33.3, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			0.8 (-5.1, 6.8)			-8.3 (-29.8, 13.1)
		P-value [a]			0.772			0.363
		Mean Diff (95% CI) [b]			9.2 (-4.9, 23.2)			
		P-value [b]			0.190			
		Effect Size (95% CI) [c]			0.45 (0.24, 0.67)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	19	19	19	4	4	4
		Mean	89.5	90.4	0.9	70.8	66.7	-4.2
		SD	17.75	16.02	6.74	25.00	30.43	20.97
		Median	100.0	100.0	0.0	83.3	66.7	0.0
		95% CI	80.9, 98.0	82.6, 98.1	-2.4, 4.1	31.1, 110.6	18.2, 115.1	-37.5, 29.2
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 0.0	58.3, 83.3	41.7, 91.7	-16.7, 8.3
		Min, Max	33.3, 100.0	50.0, 100.0	-16.7, 16.7	33.3, 83.3	33.3, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			0.9 (-2.4, 4.1)			-4.2 (-37.5, 29.2)
		P-value [a]			0.578			0.718
		Mean Diff (95% CI) [b]			5.0 (-6.5, 16.6)			
		P-value [b]			0.374			
		Effect Size (95% CI) [c]			0.25 (0.03, 0.46)			
	C21D1	N	18	18	18	4	4	4
		Mean	88.0	90.7	2.8	70.8	75.0	4.2
		SD	17.90	13.06	13.10	25.00	31.91	15.96
		Median	100.0	100.0	0.0	83.3	83.3	8.3
		95% CI	79.1, 96.9	84.2, 97.2	-3.7, 9.3	31.1, 110.6	24.2, 125.8	-21.2, 29.6
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 16.7	58.3, 83.3	50.0, 100.0	-8.3, 16.7
		Min, Max	33.3, 100.0	66.7, 100.0	-16.7, 33.3	33.3, 83.3	33.3, 100.0	-16.7, 16.7
		Mean Diff (95% CI) [a]			2.8 (-3.7, 9.3)			4.2 (-21.2, 29.6)
		P-value [a]			0.381			0.638
		Mean Diff (95% CI) [b]			-1.4 (-17.0, 14.3)			
		P-value [b]			0.855			
		Effect Size (95% CI) [c]			-0.07 (-0.28, 0.14)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	85.6	87.8	2.2	66.7	88.9	22.2
		SD	18.76	20.38	12.39	28.87	19.25	9.62
		Median	83.3	100.0	0.0	83.3	100.0	16.7
		95% CI	75.2, 95.9	76.5, 99.1	-4.6, 9.1	-5.0, 138.4	41.1, 136.7	-1.7, 46.1
		Q1, Q3	83.3, 100.0	66.7, 100.0	0.0, 0.0	33.3, 83.3	66.7, 100.0	16.7, 33.3
		Min, Max	33.3, 100.0	33.3, 100.0	-16.7, 33.3	33.3, 83.3	66.7, 100.0	16.7, 33.3
		Mean Diff (95% CI) [a]			2.2 (-4.6, 9.1)			22.2 (-1.7, 46.1)
		P-value [a]			0.499			0.057
		Mean Diff (95% CI) [b]			-20.0 (-36.2, -3.8)			
		P-value [b]			0.019			
		Effect Size (95% CI) [c]			-0.98 (-1.21, -0.76)			
	C23D1	N	11	11	11	3	3	3
		Mean	83.3	87.9	4.5	66.7	77.8	11.1
		SD	21.08	16.82	10.78	28.87	25.46	9.62
		Median	83.3	100.0	0.0	83.3	83.3	16.7
		95% CI	69.2, 97.5	76.6, 99.2	-2.7, 11.8	-5.0, 138.4	14.5, 141.0	-12.8, 35.0
		Q1, Q3	66.7, 100.0	83.3, 100.0	0.0, 16.7	33.3, 83.3	50.0, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	50.0, 100.0	-16.7, 16.7	33.3, 83.3	50.0, 100.0	0.0, 16.7
		Mean Diff (95% CI) [a]			4.5 (-2.7, 11.8)			11.1 (-12.8, 35.0)
		P-value [a]			0.192			0.184
		Mean Diff (95% CI) [b]			-6.6 (-21.6, 8.5)			
		P-value [b]			0.360			
		Effect Size (95% CI) [c]			-0.32 (-0.54, -0.11)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	85.0	90.0	5.0	58.3	66.7	8.3
		SD	21.44	21.08	8.05	35.36	47.14	11.79
		Median	91.7	100.0	0.0	58.3	66.7	8.3
		95% CI	69.7, 100.3	74.9, 105.1	-0.8, 10.8	-259.3, 376.0	-356.9, 490.2	-97.6, 114.2
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 16.7	33.3, 83.3	33.3, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	0.0, 16.7	33.3, 83.3	33.3, 100.0	0.0, 16.7
		Mean Diff (95% CI) [a]			5.0 (-0.8, 10.8)			8.3 (-97.6, 114.2)
		P-value [a]			0.081			0.500
		Mean Diff (95% CI) [b]			-3.3 (-18.0, 11.3)			
		P-value [b]			0.624			
		Effect Size (95% CI) [c]			-0.16 (-0.38, 0.05)			
	C25D1	N	9	9	9	0	0	0
		Mean	83.3	87.0	3.7	NE	NE	NE
		SD	22.05	21.70	11.11	NE	NE	NE
		Median	83.3	100.0	0.0	NE	NE	NE
		95% CI	66.4, 100.3	70.4, 103.7	-4.8, 12.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 100.0	33.3, 100.0	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			3.7 (-4.8, 12.2)			NE (NE, NE)
		P-value [a]			0.347			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	89.6	87.5	-2.1	83.3	100.0	16.7
		SD	12.40	14.77	16.52	NE	NE	NE
		Median	91.7	91.7	0.0	83.3	100.0	16.7
		95% CI	79.2, 100.0	75.1, 99.9	-15.9, 11.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	75.0, 100.0	-8.3, 8.3	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	66.7, 100.0	66.7, 100.0	-33.3, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			-2.1 (-15.9, 11.7)			16.7 (NE, NE)
		P-value [a]			0.732			NE
		Mean Diff (95% CI) [b]			-18.8 (-60.2, 22.7)			
		P-value [b]			0.320			
		Effect Size (95% CI) [c]			-0.92 (-1.15, -0.70)			
	C27D1	N	8	8	8	1	1	1
		Mean	89.6	91.7	2.1	83.3	100.0	16.7
		SD	12.40	12.60	10.68	NE	NE	NE
		Median	91.7	100.0	0.0	83.3	100.0	16.7
		95% CI	79.2, 100.0	81.1, 102.2	-6.8, 11.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 8.3	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	66.7, 100.0	66.7, 100.0	-16.7, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			2.1 (-6.8, 11.0)			16.7 (NE, NE)
		P-value [a]			0.598			NE
		Mean Diff (95% CI) [b]			-14.6 (-41.4, 12.2)			
		P-value [b]			0.239			
		Effect Size (95% CI) [c]			-0.72 (-0.94, -0.50)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	90.5	92.9	2.4	83.3	100.0	16.7
		SD	13.11	8.91	11.50	NE	NE	NE
		Median	100.0	100.0	0.0	83.3	100.0	16.7
		95% CI	78.3, 102.6	84.6, 101.1	-8.3, 13.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	83.3, 100.0	0.0, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	66.7, 100.0	83.3, 100.0	-16.7, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			2.4 (-8.3, 13.0)			16.7 (NE, NE)
		P-value [a]			0.604			NE
		Mean Diff (95% CI) [b]			-14.3 (-44.4, 15.8)			
		P-value [b]			0.289			
		Effect Size (95% CI) [c]			-0.70 (-0.92, -0.48)			
	C29D1	N	4	4	4	1	1	1
		Mean	83.3	79.2	-4.2	83.3	66.7	-16.7
		SD	13.61	8.33	8.33	NE	NE	NE
		Median	83.3	83.3	0.0	83.3	66.7	-16.7
		95% CI	61.7, 105.0	65.9, 92.4	-17.4, 9.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	75.0, 91.7	75.0, 83.3	-8.3, 0.0	83.3, 83.3	66.7, 66.7	-16.7, -16.7
		Min, Max	66.7, 100.0	66.7, 83.3	-16.7, 0.0	83.3, 83.3	66.7, 66.7	-16.7, -16.7
		Mean Diff (95% CI) [a]			-4.2 (-17.4, 9.1)			-16.7 (NE, NE)
		P-value [a]			0.391			NE
		Mean Diff (95% CI) [b]			12.5 (-17.2, 42.2)			
		P-value [b]			0.272			
		Effect Size (95% CI) [c]			0.61 (0.40, 0.83)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	87.5	83.3	-4.2	83.3	100.0	16.7
		SD	15.96	19.25	20.97	NE	NE	NE
		Median	91.7	83.3	0.0	83.3	100.0	16.7
		95% CI	62.1, 112.9	52.7, 114.0	-37.5, 29.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	75.0, 100.0	66.7, 100.0	-16.7, 8.3	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	66.7, 100.0	66.7, 100.0	-33.3, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			-4.2 (-37.5, 29.2)			16.7 (NE, NE)
		P-value [a]			0.718			NE
		Mean Diff (95% CI) [b]			-20.8 (-95.5, 53.8)			
		P-value [b]			0.440			
		Effect Size (95% CI) [c]			-1.02 (-1.25, -0.80)			
	C31D1	N	2	2	2	1	1	1
		Mean	75.0	83.3	8.3	83.3	100.0	16.7
		SD	11.79	23.57	11.79	NE	NE	NE
		Median	75.0	83.3	8.3	83.3	100.0	16.7
		95% CI	-30.9, 180.9	-128.4, 295.1	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 83.3	66.7, 100.0	0.0, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	66.7, 83.3	66.7, 100.0	0.0, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			16.7 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			-8.3 (-191.7, 175.1)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			-0.41 (-0.62, -0.19)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	75.0	83.3	8.3	83.3	100.0	16.7
		SD	11.79	23.57	11.79	NE	NE	NE
		Median	75.0	83.3	8.3	83.3	100.0	16.7
		95% CI	-30.9, 180.9	-128.4, 295.1	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 83.3	66.7, 100.0	0.0, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Min, Max	66.7, 83.3	66.7, 100.0	0.0, 16.7	83.3, 83.3	100.0, 100.0	16.7, 16.7
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			16.7 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			-8.3 (-191.7, 175.1)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			-0.41 (-0.62, -0.19)			
	C33D1	N	3	3	3	1	1	1
		Mean	83.3	88.9	5.6	83.3	83.3	0.0
		SD	16.67	19.25	9.62	NE	NE	NE
		Median	83.3	100.0	0.0	83.3	83.3	0.0
		95% CI	41.9, 124.7	41.1, 136.7	-18.3, 29.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	83.3, 83.3	83.3, 83.3	0.0, 0.0
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 16.7	83.3, 83.3	83.3, 83.3	0.0, 0.0
		Mean Diff (95% CI) [a]			5.6 (-18.3, 29.5)			0.0 (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			5.6 (-42.3, 53.4)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			0.27 (0.06, 0.49)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	83.3	88.9	5.6	NE	NE	NE
		SD	16.67	19.25	9.62	NE	NE	NE
		Median	83.3	100.0	0.0	NE	NE	NE
		95% CI	41.9, 124.7	41.1, 136.7	-18.3, 29.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			5.6 (-18.3, 29.5)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	75.0	83.3	8.3	NE	NE	NE
		SD	11.79	23.57	11.79	NE	NE	NE
		Median	75.0	83.3	8.3	NE	NE	NE
		95% CI	-30.9, 180.9	-128.4, 295.1	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 83.3	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 83.3	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	83.3	88.9	5.6	NE	NE	NE
		SD	16.67	19.25	9.62	NE	NE	NE
		Median	83.3	100.0	0.0	NE	NE	NE
		95% CI	41.9, 124.7	41.1, 136.7	-18.3, 29.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			5.6 (-18.3, 29.5)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	83.3	88.9	5.6	NE	NE	NE
		SD	16.67	19.25	9.62	NE	NE	NE
		Median	83.3	100.0	0.0	NE	NE	NE
		95% CI	41.9, 124.7	41.1, 136.7	-18.3, 29.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			5.6 (-18.3, 29.5)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	91.7	100.0	8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	91.7	100.0	8.3	NE	NE	NE
		95% CI	-14.2, 197.6	100.0, 100.0	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	91.7	100.0	8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	91.7	100.0	8.3	NE	NE	NE
		95% CI	-14.2, 197.6	100.0, 100.0	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	91.7	100.0	8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	91.7	100.0	8.3	NE	NE	NE
		95% CI	-14.2, 197.6	100.0, 100.0	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	91.7	100.0	8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	91.7	100.0	8.3	NE	NE	NE
		95% CI	-14.2, 197.6	100.0, 100.0	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 100.0	100.0, 100.0	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	83.3	100.0	16.7	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	83.3	100.0	16.7	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 83.3	100.0, 100.0	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	130	130	130	125	125	125
		Mean	84.1	80.4	-3.7	84.5	80.9	-3.6
		SD	21.25	24.60	21.19	20.21	22.67	15.92
		Median	83.3	83.3	0.0	100.0	83.3	0.0
		95% CI	80.4, 87.8	76.1, 84.7	-7.4, 0.0	81.0, 88.1	76.9, 84.9	-6.4, -0.8
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 0.0	66.7, 100.0	66.7, 100.0	-16.7, 0.0
		Min, Max	16.7, 100.0	0.0, 100.0	-66.7, 50.0	16.7, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-3.7 (-7.4, 0.0)			-3.6 (-6.4, -0.8)
		P-value [a]			0.048			0.013
		Mean Diff (95% CI) [b]			-0.1 (-4.8, 4.5)			
		P-value [b]			0.960			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.21)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	92.9	85.7	-7.1	85.2	66.7	-18.5
		SD	12.60	17.12	15.63	22.74	30.05	31.67
		Median	100.0	91.7	0.0	100.0	66.7	-16.7
		95% CI	85.6, 100.1	75.8, 95.6	-16.2, 1.9	67.7, 102.7	43.6, 89.8	-42.9, 5.8
		Q1, Q3	83.3, 100.0	66.7, 100.0	-16.7, 0.0	83.3, 100.0	66.7, 83.3	-33.3, 0.0
		Min, Max	66.7, 100.0	50.0, 100.0	-50.0, 16.7	33.3, 100.0	0.0, 100.0	-83.3, 16.7
		Mean Diff (95% CI) [a]			-7.1 (-16.2, 1.9)			-18.5 (-42.9, 5.8)
		P-value [a]			0.111			0.117
		Mean Diff (95% CI) [b]			11.4 (-9.1, 31.9)			
		P-value [b]			0.262			
		Effect Size (95% CI) [c]			0.56 (0.34, 0.78)			
Social Functioning	Baseline	N	174			164		
		Mean	75.8			74.0		
		SD	24.93			26.45		
		Median	83.3			75.0		
		95% CI	72.0, 79.5			69.9, 78.1		
		Q1, Q3	66.7, 100.0			66.7, 100.0		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	76.4	73.8	-2.6	75.1	74.9	-0.2
		SD	25.12	27.64	25.16	26.66	27.59	25.47
		95% CI	72.4, 80.5	69.4, 78.2	-6.7, 1.4	70.7, 79.5	70.3, 79.4	-4.4, 4.0
		Median	83.3	83.3	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-83.3, 66.7
		Mean Diff (95% CI) [a]			-2.6 (-6.7, 1.4)			-0.2 (-4.4, 4.0)
		P-value [a]			0.199			0.913
		Mean Diff (95% CI) [b]			-2.4 (-8.2, 3.4)			
		P-value [b]			0.416			
		Effect Size (95% CI) [c]			-0.09 (-0.31, 0.12)			
	C3D1	N	123	123	123	100	101	100
		Mean	77.9	77.6	-0.3	74.8	78.1	3.3
		SD	22.33	27.40	25.87	26.22	25.16	22.72
		95% CI	73.9, 81.9	72.8, 82.5	-4.9, 4.3	69.6, 80.0	73.1, 83.0	-1.2, 7.8
		Median	83.3	83.3	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-83.3, 50.0	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-0.3 (-4.9, 4.3)			3.3 (-1.2, 7.8)
		P-value [a]			0.908			0.146
		Mean Diff (95% CI) [b]			-3.6 (-10.1, 2.9)			
		P-value [b]			0.276			
		Effect Size (95% CI) [c]			-0.14 (-0.35, 0.07)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	93	94	93
		Mean	77.1	79.3	2.2	74.0	76.8	2.9
		SD	23.48	24.22	21.75	26.63	24.95	26.31
		95% CI	72.7, 81.5	74.8, 83.9	-1.8, 6.3	68.5, 79.5	71.7, 81.9	-2.6, 8.3
		Median	83.3	83.3	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 50.0	0.0, 100.0	0.0, 100.0	-50.0, 100.0
		Mean Diff (95% CI) [a]			2.2 (-1.8, 6.3)			2.9 (-2.6, 8.3)
		P-value [a]			0.280			0.296
		Mean Diff (95% CI) [b]			-0.6 (-7.3, 6.0)			
		P-value [b]			0.850			
		Effect Size (95% CI) [c]			-0.02 (-0.24, 0.19)			
	C5D1	N	98	98	98	80	80	80
		Mean	78.9	81.3	2.4	73.8	77.3	3.5
		SD	22.39	23.72	22.32	28.04	23.76	25.94
		95% CI	74.4, 83.4	76.5, 86.0	-2.1, 6.9	67.5, 80.0	72.0, 82.6	-2.2, 9.3
		Median	83.3	100.0	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-8.3, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 50.0	0.0, 100.0	16.7, 100.0	-50.0, 100.0
		Mean Diff (95% CI) [a]			2.4 (-2.1, 6.9)			3.5 (-2.2, 9.3)
		P-value [a]			0.294			0.226
		Mean Diff (95% CI) [b]			-1.2 (-8.3, 6.0)			
		P-value [b]			0.749			
		Effect Size (95% CI) [c]			-0.05 (-0.26, 0.17)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	68	68	68
		Mean	78.1	80.9	2.8	76.0	76.2	0.2
		SD	22.20	24.18	22.90	26.14	24.66	24.52
		95% CI	73.6, 82.6	76.0, 85.8	-1.9, 7.4	69.7, 82.3	70.3, 82.2	-5.7, 6.2
		Median	83.3	91.7	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-8.3, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 50.0	0.0, 100.0	0.0, 100.0	-50.0, 100.0
		Mean Diff (95% CI) [a]			2.8 (-1.9, 7.4)			0.2 (-5.7, 6.2)
		P-value [a]			0.238			0.935
		Mean Diff (95% CI) [b]			2.5 (-4.8, 9.9)			
		P-value [b]			0.499			
		Effect Size (95% CI) [c]			0.10 (-0.11, 0.31)			
	C7D1	N	79	79	79	52	52	52
		Mean	77.0	79.7	2.7	75.6	78.8	3.2
		SD	23.00	25.83	20.22	26.50	25.16	24.49
		95% CI	71.9, 82.2	74.0, 85.5	-1.8, 7.3	68.3, 83.0	71.8, 85.9	-3.6, 10.0
		Median	83.3	83.3	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	0.0, 8.3
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 50.0	0.0, 100.0	16.7, 100.0	-50.0, 100.0
		Mean Diff (95% CI) [a]			2.7 (-1.8, 7.3)			3.2 (-3.6, 10.0)
		P-value [a]			0.232			0.350
		Mean Diff (95% CI) [b]			-0.5 (-8.2, 7.3)			
		P-value [b]			0.907			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.19)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	75	75	75	50	50	50
		Mean	75.3	80.4	5.1	75.0	78.3	3.3
		SD	23.79	26.05	21.74	26.78	27.61	29.35
		95% CI	69.9, 80.8	74.5, 86.4	0.1, 10.1	67.4, 82.6	70.5, 86.2	-5.0, 11.7
		Median	66.7	100.0	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 50.0	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			5.1 (0.1, 10.1)			3.3 (-5.0, 11.7)
		P-value [a]			0.045			0.426
		Mean Diff (95% CI) [b]			1.8 (-7.3, 10.8)			
		P-value [b]			0.698			
		Effect Size (95% CI) [c]			0.07 (-0.14, 0.28)			
	C9D1	N	60	60	60	42	42	42
		Mean	77.5	80.6	3.1	74.6	80.2	5.6
		SD	22.09	25.89	21.37	26.86	23.92	28.91
		95% CI	71.8, 83.2	73.9, 87.2	-2.5, 8.6	66.2, 83.0	72.7, 87.6	-3.5, 14.6
		Median	83.3	100.0	0.0	75.0	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 16.7
		Min, Max	33.3, 100.0	0.0, 100.0	-66.7, 50.0	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			3.1 (-2.5, 8.6)			5.6 (-3.5, 14.6)
		P-value [a]			0.273			0.220
		Mean Diff (95% CI) [b]			-2.5 (-12.4, 7.4)			
		P-value [b]			0.617			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.12)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	76.2	85.8	9.6	72.8	66.7	-6.1
		SD	22.34	19.54	16.38	24.56	30.95	28.53
		95% CI	70.1, 82.3	80.5, 91.1	5.1, 14.0	63.6, 81.9	55.1, 78.2	-16.8, 4.5
		Median	75.0	100.0	0.0	66.7	66.7	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	50.0, 100.0	-33.3, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	-16.7, 33.3	0.0, 100.0	0.0, 100.0	-66.7, 50.0
		Mean Diff (95% CI) [a]			9.6 (5.1, 14.0)			-6.1 (-16.8, 4.5)
		P-value [a]			<.001			0.250
		Mean Diff (95% CI) [b]			15.7 (5.9, 25.4)			
		P-value [b]			0.002			
		Effect Size (95% CI) [c]			0.61 (0.39, 0.83)			
	C11D1	N	46	46	46	23	23	23
		Mean	75.4	78.6	3.3	79.0	79.0	0.0
		SD	21.87	24.00	26.44	18.95	24.21	26.11
		95% CI	68.9, 81.9	71.5, 85.8	-4.6, 11.1	70.8, 87.2	68.5, 89.5	-11.3, 11.3
		Median	66.7	83.3	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 16.7
		Min, Max	33.3, 100.0	0.0, 100.0	-66.7, 66.7	33.3, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			3.3 (-4.6, 11.1)			0.0 (-11.3, 11.3)
		P-value [a]			0.407			1.000
		Mean Diff (95% CI) [b]			3.3 (-10.2, 16.7)			
		P-value [b]			0.629			
		Effect Size (95% CI) [c]			0.13 (-0.09, 0.34)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	40	40	40	19	19	19
		Mean	75.8	80.8	5.0	82.5	87.7	5.3
		SD	21.33	25.47	25.09	15.19	19.12	21.55
		95% CI	69.0, 82.7	72.7, 89.0	-3.0, 13.0	75.1, 89.8	78.5, 96.9	-5.1, 15.7
		Median	66.7	100.0	0.0	83.3	100.0	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	0.0, 33.3
		Min, Max	33.3, 100.0	0.0, 100.0	-50.0, 66.7	66.7, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			5.0 (-3.0, 13.0)			5.3 (-5.1, 15.7)
		P-value [a]			0.215			0.301
		Mean Diff (95% CI) [b]			-0.3 (-13.7, 13.1)			
		P-value [b]			0.969			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.20)			
	C13D1	N	33	33	33	15	15	15
		Mean	76.8	84.3	7.6	81.1	83.3	2.2
		SD	22.02	19.07	25.72	16.51	17.82	25.09
		95% CI	69.0, 84.6	77.6, 91.1	-1.5, 16.7	72.0, 90.3	73.5, 93.2	-11.7, 16.1
		Median	83.3	100.0	0.0	83.3	83.3	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 33.3
		Min, Max	33.3, 100.0	33.3, 100.0	-33.3, 66.7	50.0, 100.0	50.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			7.6 (-1.5, 16.7)			2.2 (-11.7, 16.1)
		P-value [a]			0.100			0.737
		Mean Diff (95% CI) [b]			5.4 (-10.6, 21.4)			
		P-value [b]			0.504			
		Effect Size (95% CI) [c]			0.21 (-0.01, 0.42)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	76.8	80.3	3.5	80.6	84.7	4.2
		SD	22.02	19.30	19.44	17.16	21.86	26.71
		95% CI	69.0, 84.6	73.5, 87.1	-3.4, 10.4	69.6, 91.5	70.8, 98.6	-12.8, 21.1
		Median	83.3	66.7	0.0	83.3	100.0	8.3
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	66.7, 100.0	66.7, 100.0	-8.3, 25.0
		Min, Max	33.3, 100.0	50.0, 100.0	-33.3, 50.0	50.0, 100.0	33.3, 100.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			3.5 (-3.4, 10.4)			4.2 (-12.8, 21.1)
		P-value [a]			0.304			0.600
		Mean Diff (95% CI) [b]			-0.6 (-15.3, 14.0)			
		P-value [b]			0.931			
		Effect Size (95% CI) [c]			-0.02 (-0.24, 0.19)			
	C15D1	N	28	28	28	13	13	13
		Mean	75.6	74.4	-1.2	80.8	82.1	1.3
		SD	21.98	21.98	25.23	16.45	20.93	20.93
		95% CI	67.1, 84.1	65.9, 82.9	-11.0, 8.6	70.8, 90.7	69.4, 94.7	-11.4, 13.9
		Median	75.0	66.7	0.0	83.3	100.0	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-8.3, 8.3	66.7, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	0.0, 100.0	-83.3, 33.3	50.0, 100.0	50.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-1.2 (-11.0, 8.6)			1.3 (-11.4, 13.9)
		P-value [a]			0.805			0.829
		Mean Diff (95% CI) [b]			-2.5 (-18.8, 13.8)			
		P-value [b]			0.760			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.12)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	76.2	78.0	1.8	78.3	86.7	8.3
		SD	22.42	22.70	22.38	15.81	15.32	18.00
		95% CI	67.5, 84.9	69.2, 86.8	-6.9, 10.5	67.0, 89.6	75.7, 97.6	-4.5, 21.2
		Median	75.0	83.3	0.0	83.3	91.7	8.3
		Q1, Q3	66.7, 100.0	66.7, 100.0	-8.3, 16.7	66.7, 83.3	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	-50.0, 50.0	50.0, 100.0	66.7, 100.0	-16.7, 33.3
		Mean Diff (95% CI) [a]			1.8 (-6.9, 10.5)			8.3 (-4.5, 21.2)
		P-value [a]			0.676			0.177
		Mean Diff (95% CI) [b]			-6.5 (-22.5, 9.4)			
		P-value [b]			0.411			
		Effect Size (95% CI) [c]			-0.25 (-0.47, -0.04)			
	C17D1	N	26	26	26	7	7	7
		Mean	74.4	76.3	1.9	73.8	81.0	7.1
		SD	22.23	27.56	21.25	16.27	27.94	25.20
		95% CI	65.4, 83.3	65.2, 87.4	-6.7, 10.5	58.8, 88.9	55.1, 106.8	-16.2, 30.4
		Median	66.7	83.3	0.0	66.7	100.0	16.7
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 83.3	50.0, 100.0	-16.7, 33.3
		Min, Max	33.3, 100.0	0.0, 100.0	-33.3, 50.0	50.0, 100.0	33.3, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			1.9 (-6.7, 10.5)			7.1 (-16.2, 30.4)
		P-value [a]			0.649			0.482
		Mean Diff (95% CI) [b]			-5.2 (-24.4, 13.9)			
		P-value [b]			0.583			
		Effect Size (95% CI) [c]			-0.20 (-0.42, 0.01)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	72.0	78.8	6.8	76.2	83.3	7.1
		SD	22.65	24.76	21.61	16.27	21.52	21.21
		95% CI	61.9, 82.0	67.8, 89.8	-2.8, 16.4	61.1, 91.2	63.4, 103.2	-12.5, 26.8
		Median	66.7	83.3	0.0	83.3	100.0	16.7
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 33.3	66.7, 83.3	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	0.0, 100.0	-33.3, 50.0	50.0, 100.0	50.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			6.8 (-2.8, 16.4)			7.1 (-12.5, 26.8)
		P-value [a]			0.154			0.407
		Mean Diff (95% CI) [b]			-0.3 (-19.5, 18.8)			
		P-value [b]			0.973			
		Effect Size (95% CI) [c]			-0.01 (-0.23, 0.20)			
	C19D1	N	20	20	20	6	6	6
		Mean	72.5	76.7	4.2	75.0	86.1	11.1
		SD	23.74	20.52	22.21	17.48	22.15	25.09
		95% CI	61.4, 83.6	67.1, 86.3	-6.2, 14.6	56.7, 93.3	62.9, 109.4	-15.2, 37.4
		Median	66.7	66.7	0.0	75.0	100.0	16.7
		Q1, Q3	58.3, 100.0	66.7, 100.0	-8.3, 8.3	66.7, 83.3	66.7, 100.0	0.0, 33.3
		Min, Max	33.3, 100.0	33.3, 100.0	-33.3, 50.0	50.0, 100.0	50.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			4.2 (-6.2, 14.6)			11.1 (-15.2, 37.4)
		P-value [a]			0.412			0.328
		Mean Diff (95% CI) [b]			-6.9 (-28.9, 15.0)			
		P-value [b]			0.520			
		Effect Size (95% CI) [c]			-0.27 (-0.48, -0.06)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	19	19	19	4	4	4
		Mean	76.3	78.1	1.8	75.0	70.8	-4.2
		SD	23.12	24.25	20.71	21.52	20.97	20.97
		95% CI	65.2, 87.5	66.4, 89.8	-8.2, 11.7	40.8, 109.2	37.5, 104.2	-37.5, 29.2
		Median	83.3	83.3	0.0	75.0	66.7	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 0.0	58.3, 91.7	58.3, 83.3	-16.7, 8.3
		Min, Max	33.3, 100.0	16.7, 100.0	-33.3, 50.0	50.0, 100.0	50.0, 100.0	-33.3, 16.7
		Mean Diff (95% CI) [a]			1.8 (-8.2, 11.7)			-4.2 (-37.5, 29.2)
		P-value [a]			0.716			0.718
		Mean Diff (95% CI) [b]			5.9 (-17.8, 29.7)			
		P-value [b]			0.609			
		Effect Size (95% CI) [c]			0.23 (0.02, 0.44)			
	C21D1	N	18	18	18	4	4	4
		Mean	73.1	81.5	8.3	75.0	75.0	0.0
		SD	22.24	19.71	21.58	21.52	16.67	13.61
		95% CI	62.1, 84.2	71.7, 91.3	-2.4, 19.1	40.8, 109.2	48.5, 101.5	-21.7, 21.7
		Median	66.7	83.3	0.0	75.0	66.7	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 33.3	58.3, 91.7	66.7, 83.3	-8.3, 8.3
		Min, Max	33.3, 100.0	50.0, 100.0	-33.3, 50.0	50.0, 100.0	66.7, 100.0	-16.7, 16.7
		Mean Diff (95% CI) [a]			8.3 (-2.4, 19.1)			0.0 (-21.7, 21.7)
		P-value [a]			0.120			1.000
		Mean Diff (95% CI) [b]			8.3 (-15.4, 32.1)			
		P-value [b]			0.472			
		Effect Size (95% CI) [c]			0.32 (0.11, 0.54)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	77.8	76.7	-1.1	72.2	77.8	5.6
		SD	20.57	21.64	18.33	25.46	19.25	9.62
		95% CI	66.4, 89.2	64.7, 88.7	-11.3, 9.0	9.0, 135.5	30.0, 125.6	-18.3, 29.5
		Median	83.3	83.3	0.0	66.7	66.7	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 0.0	50.0, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	-50.0, 33.3	50.0, 100.0	66.7, 100.0	0.0, 16.7
		Mean Diff (95% CI) [a]			-1.1 (-11.3, 9.0)			5.6 (-18.3, 29.5)
		P-value [a]			0.818			0.423
		Mean Diff (95% CI) [b]			-6.7 (-30.1, 16.8)			
		P-value [b]			0.555			
		Effect Size (95% CI) [c]			-0.26 (-0.47, -0.05)			
	C23D1	N	11	11	11	3	3	3
		Mean	74.2	83.3	9.1	72.2	77.8	5.6
		SD	21.56	18.26	18.80	25.46	19.25	9.62
		95% CI	59.8, 88.7	71.1, 95.6	-3.5, 21.7	9.0, 135.5	30.0, 125.6	-18.3, 29.5
		Median	66.7	83.3	16.7	66.7	66.7	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	50.0, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	50.0, 100.0	-33.3, 33.3	50.0, 100.0	66.7, 100.0	0.0, 16.7
		Mean Diff (95% CI) [a]			9.1 (-3.5, 21.7)			5.6 (-18.3, 29.5)
		P-value [a]			0.140			0.423
		Mean Diff (95% CI) [b]			3.5 (-21.5, 28.5)			
		P-value [b]			0.763			
		Effect Size (95% CI) [c]			0.14 (-0.08, 0.35)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	75.0	78.3	3.3	75.0	83.3	8.3
		SD	22.57	22.29	15.32	35.36	23.57	11.79
		95% CI	58.9, 91.1	62.4, 94.3	-7.6, 14.3	-242.7, 392.7	-128.4, 295.1	-97.6, 114.2
		Median	75.0	75.0	0.0	75.0	83.3	8.3
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 16.7	50.0, 100.0	66.7, 100.0	0.0, 16.7
		Min, Max	33.3, 100.0	33.3, 100.0	-16.7, 33.3	50.0, 100.0	66.7, 100.0	0.0, 16.7
		Mean Diff (95% CI) [a]			3.3 (-7.6, 14.3)			8.3 (-97.6, 114.2)
		P-value [a]			0.509			0.500
		Mean Diff (95% CI) [b]			-5.0 (-30.9, 20.9)			
		P-value [b]			0.676			
		Effect Size (95% CI) [c]			-0.19 (-0.41, 0.02)			
	C25D1	N	9	9	9	0	0	0
		Mean	72.2	74.1	1.9	NE	NE	NE
		SD	22.05	23.73	13.03	NE	NE	NE
		95% CI	55.3, 89.2	55.8, 92.3	-8.2, 11.9	NE, NE	NE, NE	NE, NE
		Median	66.7	66.7	0.0	NE	NE	NE
		Q1, Q3	66.7, 83.3	66.7, 100.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 100.0	33.3, 100.0	-16.7, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			1.9 (-8.2, 11.9)			NE (NE, NE)
		P-value [a]			0.681			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	83.3	81.3	-2.1	100.0	100.0	0.0
		SD	15.43	30.13	31.42	NE	NE	NE
		95% CI	70.4, 96.2	56.1, 106.4	-28.3, 24.2	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	0.0	100.0	100.0	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-8.3, 16.7	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	66.7, 100.0	16.7, 100.0	-66.7, 33.3	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-2.1 (-28.3, 24.2)			0.0 (NE, NE)
		P-value [a]			0.857			NE
		Mean Diff (95% CI) [b]			-2.1 (-80.9, 76.7)			
		P-value [b]			0.952			
		Effect Size (95% CI) [c]			-0.08 (-0.29, 0.13)			
	C27D1	N	8	8	8	1	1	1
		Mean	83.3	85.4	2.1	100.0	100.0	0.0
		SD	15.43	16.52	16.52	NE	NE	NE
		95% CI	70.4, 96.2	71.6, 99.2	-11.7, 15.9	NE, NE	NE, NE	NE, NE
		Median	83.3	91.7	0.0	100.0	100.0	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-8.3, 8.3	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	66.7, 100.0	66.7, 100.0	-16.7, 33.3	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			2.1 (-11.7, 15.9)			0.0 (NE, NE)
		P-value [a]			0.732			NE
		Mean Diff (95% CI) [b]			2.1 (-39.3, 43.5)			
		P-value [b]			0.909			
		Effect Size (95% CI) [c]			0.08 (-0.13, 0.29)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	83.3	85.7	2.4	100.0	100.0	0.0
		SD	16.67	17.82	15.00	NE	NE	NE
		95% CI	67.9, 98.7	69.2, 102.2	-11.5, 16.2	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	0.0	100.0	100.0	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 0.0	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	66.7, 100.0	66.7, 100.0	-16.7, 33.3	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			2.4 (-11.5, 16.2)			0.0 (NE, NE)
		P-value [a]			0.689			NE
		Mean Diff (95% CI) [b]			2.4 (-36.8, 41.6)			
		P-value [b]			0.887			
		Effect Size (95% CI) [c]			0.09 (-0.12, 0.31)			
	C29D1	N	4	4	4	1	1	1
		Mean	70.8	70.8	0.0	100.0	66.7	-33.3
		SD	8.33	25.00	30.43	NE	NE	NE
		95% CI	57.6, 84.1	31.1, 110.6	-48.4, 48.4	NE, NE	NE, NE	NE, NE
		Median	66.7	66.7	0.0	100.0	66.7	-33.3
		Q1, Q3	66.7, 75.0	50.0, 91.7	-25.0, 25.0	100.0, 100.0	66.7, 66.7	-33.3, -33.3
		Min, Max	66.7, 83.3	50.0, 100.0	-33.3, 33.3	100.0, 100.0	66.7, 66.7	-33.3, -33.3
		Mean Diff (95% CI) [a]			0.0 (-48.4, 48.4)			-33.3 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			33.3 (-74.9, 141.6)			
		P-value [b]			0.399			
		Effect Size (95% CI) [c]			1.30 (1.06, 1.53)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	79.2	87.5	8.3	100.0	50.0	-50.0
		SD	15.96	15.96	21.52	NE	NE	NE
		95% CI	53.8, 104.6	62.1, 112.9	-25.9, 42.6	NE, NE	NE, NE	NE, NE
		Median	75.0	91.7	8.3	100.0	50.0	-50.0
		Q1, Q3	66.7, 91.7	75.0, 100.0	-8.3, 25.0	100.0, 100.0	50.0, 50.0	-50.0, -50.0
		Min, Max	66.7, 100.0	66.7, 100.0	-16.7, 33.3	100.0, 100.0	50.0, 50.0	-50.0, -50.0
		Mean Diff (95% CI) [a]			8.3 (-25.9, 42.6)			-50.0 (NE, NE)
		P-value [a]			0.495			NE
		Mean Diff (95% CI) [b]			58.3 (-18.2, 134.9)			
		P-value [b]			0.094			
		Effect Size (95% CI) [c]			2.27 (1.99, 2.54)			
	C31D1	N	2	2	2	1	1	1
		Mean	66.7	91.7	25.0	100.0	83.3	-16.7
		SD	0.00	11.79	11.79	NE	NE	NE
		95% CI	66.7, 66.7	-14.2, 197.6	-80.9, 130.9	NE, NE	NE, NE	NE, NE
		Median	66.7	91.7	25.0	100.0	83.3	-16.7
		Q1, Q3	66.7, 66.7	83.3, 100.0	16.7, 33.3	100.0, 100.0	83.3, 83.3	-16.7, -16.7
		Min, Max	66.7, 66.7	83.3, 100.0	16.7, 33.3	100.0, 100.0	83.3, 83.3	-16.7, -16.7
		Mean Diff (95% CI) [a]			25.0 (-80.9, 130.9)			-16.7 (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			41.7 (-141.7, 225.1)			
		P-value [b]			0.212			
		Effect Size (95% CI) [c]			1.62 (1.37, 1.86)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	66.7	83.3	16.7	100.0	83.3	-16.7
		SD	0.00	23.57	23.57	NE	NE	NE
		95% CI	66.7, 66.7	-128.4, 295.1	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	66.7	83.3	16.7	100.0	83.3	-16.7
		Q1, Q3	66.7, 66.7	66.7, 100.0	0.0, 33.3	100.0, 100.0	83.3, 83.3	-16.7, -16.7
		Min, Max	66.7, 66.7	66.7, 100.0	0.0, 33.3	100.0, 100.0	83.3, 83.3	-16.7, -16.7
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			-16.7 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			33.3 (-333.5, 400.1)			
		P-value [b]			0.454			
		Effect Size (95% CI) [c]			1.30 (1.06, 1.53)			
	C33D1	N	3	3	3	1	1	1
		Mean	77.8	88.9	11.1	100.0	100.0	0.0
		SD	19.25	19.25	19.25	NE	NE	NE
		95% CI	30.0, 125.6	41.1, 136.7	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	66.7	100.0	0.0	100.0	100.0	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 33.3	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 33.3	100.0, 100.0	100.0, 100.0	0.0, 0.0
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			0.0 (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			11.1 (-84.5, 106.7)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			0.43 (0.22, 0.65)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	77.8	88.9	11.1	NE	NE	NE
		SD	19.25	19.25	19.25	NE	NE	NE
		95% CI	30.0, 125.6	41.1, 136.7	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	66.7	100.0	0.0	NE	NE	NE
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	66.7	83.3	16.7	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		95% CI	66.7, 66.7	-128.4, 295.1	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	66.7	83.3	16.7	NE	NE	NE
		Q1, Q3	66.7, 66.7	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 66.7	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	77.8	88.9	11.1	NE	NE	NE
		SD	19.25	19.25	19.25	NE	NE	NE
		95% CI	30.0, 125.6	41.1, 136.7	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	66.7	100.0	0.0	NE	NE	NE
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	77.8	88.9	11.1	NE	NE	NE
		SD	19.25	19.25	19.25	NE	NE	NE
		95% CI	30.0, 125.6	41.1, 136.7	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	66.7	100.0	0.0	NE	NE	NE
		Q1, Q3	66.7, 100.0	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	66.7, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	23.57	0.00	23.57	NE	NE	NE
		95% CI	-128.4, 295.1	100.0, 100.0	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	16.7	NE	NE	NE
		Q1, Q3	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	23.57	0.00	23.57	NE	NE	NE
		95% CI	-128.4, 295.1	100.0, 100.0	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	16.7	NE	NE	NE
		Q1, Q3	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	23.57	0.00	23.57	NE	NE	NE
		95% CI	-128.4, 295.1	100.0, 100.0	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	16.7	NE	NE	NE
		Q1, Q3	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	83.3	100.0	16.7	NE	NE	NE
		SD	23.57	0.00	23.57	NE	NE	NE
		95% CI	-128.4, 295.1	100.0, 100.0	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	83.3	100.0	16.7	NE	NE	NE
		Q1, Q3	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 100.0	100.0, 100.0	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	66.7	100.0	33.3	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	66.7	100.0	33.3	NE	NE	NE
		Q1, Q3	66.7, 66.7	100.0, 100.0	33.3, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 66.7	100.0, 100.0	33.3, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			33.3 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	66.7	100.0	33.3	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	66.7	100.0	33.3	NE	NE	NE
		Q1, Q3	66.7, 66.7	100.0, 100.0	33.3, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	66.7, 66.7	100.0, 100.0	33.3, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			33.3 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	130	130	130	124	124	124
		Mean	76.8	70.8	-6.0	76.3	73.5	-2.8
		SD	26.45	32.35	31.13	25.33	28.83	26.35
		95% CI	72.2, 81.4	65.2, 76.4	-11.4, -0.6	71.8, 80.8	68.4, 78.6	-7.5, 1.9
		Median	83.3	83.3	0.0	83.3	75.0	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-16.7, 16.7	66.7, 100.0	66.7, 100.0	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 83.3
		Mean Diff (95% CI) [a]			-6.0 (-11.4, -0.6)			-2.8 (-7.5, 1.9)
		P-value [a]			0.029			0.235
		Mean Diff (95% CI) [b]			-3.2 (-10.3, 3.9)			
		P-value [b]			0.378			
		Effect Size (95% CI) [c]			-0.12 (-0.34, 0.09)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	84.5	75.0	-9.5	70.4	61.1	-9.3
		SD	13.81	20.41	21.40	21.70	33.33	26.50
		95% CI	76.5, 92.5	63.2, 86.8	-21.9, 2.8	53.7, 87.0	35.5, 86.7	-29.6, 11.1
		Median	83.3	66.7	-8.3	66.7	66.7	0.0
		Q1, Q3	66.7, 100.0	66.7, 100.0	-33.3, 16.7	66.7, 83.3	66.7, 66.7	-16.7, 0.0
		Min, Max	66.7, 100.0	33.3, 100.0	-33.3, 16.7	33.3, 100.0	0.0, 100.0	-66.7, 16.7
		Mean Diff (95% CI) [a]			-9.5 (-21.9, 2.8)			-9.3 (-29.6, 11.1)
		P-value [a]			0.120			0.325
		Mean Diff (95% CI) [b]			-0.3 (-21.1, 20.6)			
		P-value [b]			0.979			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.20)			
Fatigue	Baseline	N	174			165		
		Mean	34.9			35.0		
		SD	24.20			23.81		
		95% CI	31.2, 38.5			31.4, 38.7		
		Median	33.3			33.3		
		Q1, Q3	22.2, 44.4			22.2, 44.4		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	33.6	39.0	5.4	35.0	42.6	7.6
		SD	23.61	25.63	21.64	24.62	25.17	19.91
		Median	33.3	33.3	0.0	33.3	33.3	11.1
		95% CI	29.8, 37.4	34.9, 43.1	1.9, 8.8	30.9, 39.0	38.4, 46.7	4.4, 10.9
		Q1, Q3	22.2, 44.4	22.2, 55.6	0.0, 16.7	11.1, 44.4	22.2, 55.6	0.0, 22.2
		Min, Max	0.0, 100.0	0.0, 100.0	-55.6, 100.0	0.0, 100.0	0.0, 100.0	-55.6, 88.9
		Mean Diff (95% CI) [a]			5.4 (1.9, 8.8)			7.6 (4.4, 10.9)
		P-value [a]			0.003			<.001
		Mean Diff (95% CI) [b]			-2.3 (-7.0, 2.5)			
		P-value [b]			0.350			
		Effect Size (95% CI) [c]			-0.09 (-0.31, 0.12)			
	C3D1	N	124	124	124	102	102	102
		Mean	33.4	35.0	1.6	34.3	36.7	2.4
		SD	23.00	25.57	22.77	21.95	23.07	17.17
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	29.3, 37.5	30.4, 39.5	-2.5, 5.6	30.0, 38.6	32.2, 41.2	-1.0, 5.8
		Q1, Q3	22.2, 44.4	22.2, 50.0	-11.1, 11.1	22.2, 44.4	22.2, 44.4	0.0, 11.1
		Min, Max	0.0, 100.0	0.0, 100.0	-77.8, 66.7	0.0, 88.9	0.0, 88.9	-44.4, 55.6
		Mean Diff (95% CI) [a]			1.6 (-2.5, 5.6)			2.4 (-1.0, 5.8)
		P-value [a]			0.445			0.162
		Mean Diff (95% CI) [b]			-0.8 (-6.2, 4.6)			
		P-value [b]			0.762			
		Effect Size (95% CI) [c]			-0.03 (-0.25, 0.18)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	34.6	32.0	-2.6	34.0	33.9	-0.1
		SD	23.76	24.54	20.06	22.39	24.52	22.55
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	30.2, 39.1	27.4, 36.6	-6.3, 1.2	29.5, 38.6	28.9, 38.9	-4.7, 4.5
		Q1, Q3	22.2, 44.4	11.1, 44.4	-11.1, 11.1	11.1, 44.4	11.1, 44.4	-11.1, 11.1
		Min, Max	0.0, 100.0	0.0, 100.0	-77.8, 33.3	0.0, 88.9	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-2.6 (-6.3, 1.2)			-0.1 (-4.7, 4.5)
		P-value [a]			0.176			0.960
		Mean Diff (95% CI) [b]			-2.5 (-8.3, 3.4)			
		P-value [b]			0.408			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.11)			
	C5D1	N	97	97	97	80	80	80
		Mean	34.0	33.0	-1.0	34.2	34.3	0.1
		SD	24.21	24.95	22.41	22.62	23.53	19.41
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	29.1, 38.9	28.0, 38.1	-5.5, 3.5	29.1, 39.2	29.1, 39.5	-4.2, 4.5
		Q1, Q3	22.2, 44.4	11.1, 44.4	-11.1, 11.1	11.1, 44.4	22.2, 44.4	-11.1, 11.1
		Min, Max	0.0, 100.0	0.0, 100.0	-77.8, 55.6	0.0, 88.9	0.0, 100.0	-55.6, 44.4
		Mean Diff (95% CI) [a]			-1.0 (-5.5, 3.5)			0.1 (-4.2, 4.5)
		P-value [a]			0.670			0.949
		Mean Diff (95% CI) [b]			-1.1 (-7.4, 5.2)			
		P-value [b]			0.728			
		Effect Size (95% CI) [c]			-0.05 (-0.26, 0.17)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	69	69	69
		Mean	32.3	29.2	-3.1	33.8	35.5	1.7
		SD	23.20	22.76	22.32	22.01	26.01	20.64
		Median	33.3	22.2	0.0	33.3	33.3	0.0
		95% CI	27.6, 37.0	24.6, 33.8	-7.6, 1.4	28.5, 39.1	29.3, 41.8	-3.3, 6.6
		Q1, Q3	22.2, 44.4	11.1, 38.9	-11.1, 11.1	11.1, 44.4	16.7, 55.6	-11.1, 11.1
		Min, Max	0.0, 100.0	0.0, 100.0	-77.8, 55.6	0.0, 88.9	0.0, 100.0	-66.7, 55.6
		Mean Diff (95% CI) [a]			-3.1 (-7.6, 1.4)			1.7 (-3.3, 6.6)
		P-value [a]			0.173			0.499
		Mean Diff (95% CI) [b]			-4.8 (-11.6, 1.9)			
		P-value [b]			0.160			
		Effect Size (95% CI) [c]			-0.20 (-0.41, 0.01)			
	C7D1	N	79	79	79	53	53	53
		Mean	33.1	30.1	-3.0	34.6	28.5	-6.1
		SD	23.53	25.23	19.39	23.54	21.41	20.51
		Median	33.3	22.2	0.0	33.3	33.3	0.0
		95% CI	27.8, 38.3	24.4, 35.8	-7.3, 1.4	28.1, 41.1	22.6, 34.4	-11.7, -0.4
		Q1, Q3	22.2, 44.4	11.1, 44.4	-11.1, 11.1	11.1, 44.4	11.1, 44.4	-22.2, 11.1
		Min, Max	0.0, 88.9	0.0, 88.9	-77.8, 44.4	0.0, 88.9	0.0, 66.7	-55.6, 33.3
		Mean Diff (95% CI) [a]			-3.0 (-7.3, 1.4)			-6.1 (-11.7, -0.4)
		P-value [a]			0.180			0.036
		Mean Diff (95% CI) [b]			3.1 (-3.8, 10.1)			
		P-value [b]			0.377			
		Effect Size (95% CI) [c]			0.13 (-0.08, 0.34)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	32.6	28.7	-3.9	34.7	33.1	-1.6
		SD	23.40	24.63	19.93	24.14	21.70	20.33
		Median	33.3	22.2	0.0	33.3	33.3	0.0
		95% CI	27.3, 37.9	23.0, 34.3	-8.5, 0.6	27.8, 41.5	26.9, 39.3	-7.3, 4.2
		Q1, Q3	22.2, 44.4	11.1, 33.3	-11.1, 0.0	11.1, 44.4	11.1, 44.4	-11.1, 11.1
		Min, Max	0.0, 88.9	0.0, 100.0	-55.6, 66.7	0.0, 88.9	0.0, 100.0	-55.6, 44.4
		Mean Diff (95% CI) [a]			-3.9 (-8.5, 0.6)			-1.6 (-7.3, 4.2)
		P-value [a]			0.088			0.591
		Mean Diff (95% CI) [b]			-2.4 (-9.6, 4.8)			
		P-value [b]			0.514			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.11)			
	C9D1	N	60	60	60	42	42	42
		Mean	30.9	28.9	-2.0	36.2	33.1	-3.2
		SD	22.88	24.74	20.91	25.03	23.34	19.52
		Median	33.3	22.2	0.0	33.3	33.3	0.0
		95% CI	25.0, 36.8	22.5, 35.3	-7.4, 3.4	28.4, 44.0	25.8, 40.3	-9.3, 2.9
		Q1, Q3	16.7, 44.4	11.1, 44.4	-16.7, 11.1	11.1, 55.6	11.1, 55.6	-11.1, 0.0
		Min, Max	0.0, 88.9	0.0, 100.0	-44.4, 66.7	0.0, 88.9	0.0, 88.9	-55.6, 44.4
		Mean Diff (95% CI) [a]			-2.0 (-7.4, 3.4)			-3.2 (-9.3, 2.9)
		P-value [a]			0.454			0.298
		Mean Diff (95% CI) [b]			1.1 (-7.0, 9.3)			
		P-value [b]			0.782			
		Effect Size (95% CI) [c]			0.05 (-0.17, 0.26)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	31.7	26.7	-4.9	39.6	40.0	0.4
		SD	24.27	21.64	18.90	24.53	23.99	19.68
		Median	33.3	22.2	0.0	33.3	33.3	0.0
		95% CI	25.1, 38.3	20.8, 32.7	-10.1, 0.2	30.5, 48.8	31.0, 49.0	-7.0, 7.7
		Q1, Q3	11.1, 44.4	11.1, 33.3	-22.2, 11.1	22.2, 66.7	33.3, 66.7	-11.1, 0.0
		Min, Max	0.0, 88.9	0.0, 100.0	-44.4, 33.3	0.0, 88.9	0.0, 88.9	-33.3, 55.6
		Mean Diff (95% CI) [a]			-4.9 (-10.1, 0.2)			0.4 (-7.0, 7.7)
		P-value [a]			0.060			0.919
		Mean Diff (95% CI) [b]			-5.3 (-14.0, 3.4)			
		P-value [b]			0.228			
		Effect Size (95% CI) [c]			-0.22 (-0.43, -0.01)			
	C11D1	N	45	45	45	23	23	23
		Mean	32.3	28.1	-4.2	33.3	28.5	-4.8
		SD	24.37	21.53	21.49	21.97	16.69	24.12
		Median	33.3	22.2	0.0	33.3	33.3	0.0
		95% CI	25.0, 39.7	21.7, 34.6	-10.7, 2.3	23.8, 42.8	21.3, 35.7	-15.3, 5.6
		Q1, Q3	11.1, 44.4	11.1, 44.4	-11.1, 0.0	11.1, 44.4	22.2, 33.3	-11.1, 11.1
		Min, Max	0.0, 88.9	0.0, 77.8	-55.6, 44.4	0.0, 77.8	0.0, 66.7	-77.8, 22.2
		Mean Diff (95% CI) [a]			-4.2 (-10.7, 2.3)			-4.8 (-15.3, 5.6)
		P-value [a]			0.197			0.347
		Mean Diff (95% CI) [b]			0.6 (-10.8, 12.1)			
		P-value [b]			0.912			
		Effect Size (95% CI) [c]			0.03 (-0.19, 0.24)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	30.1	24.1	-6.0	32.2	28.7	-3.5
		SD	23.47	21.21	21.96	19.91	21.70	22.54
		Median	33.3	22.2	0.0	33.3	33.3	0.0
		95% CI	22.7, 37.5	17.4, 30.8	-12.9, 1.0	22.6, 41.8	18.2, 39.1	-14.4, 7.4
		Q1, Q3	11.1, 44.4	0.0, 33.3	-22.2, 0.0	11.1, 44.4	11.1, 33.3	-11.1, 11.1
		Min, Max	0.0, 88.9	0.0, 77.8	-55.6, 44.4	0.0, 77.8	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			-6.0 (-12.9, 1.0)			-3.5 (-14.4, 7.4)
		P-value [a]			0.090			0.506
		Mean Diff (95% CI) [b]			-2.5 (-14.8, 9.8)			
		P-value [b]			0.691			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.11)			
	C13D1	N	32	32	32	15	15	15
		Mean	30.6	26.0	-4.5	35.6	33.3	-2.2
		SD	23.44	22.15	23.42	23.83	23.38	29.46
		Median	33.3	22.2	-11.1	33.3	33.3	0.0
		95% CI	22.1, 39.0	18.1, 34.0	-13.0, 3.9	22.4, 48.8	20.4, 46.3	-18.5, 14.1
		Q1, Q3	11.1, 50.0	0.0, 38.9	-22.2, 5.6	11.1, 55.6	22.2, 33.3	-33.3, 22.2
		Min, Max	0.0, 77.8	0.0, 77.8	-55.6, 55.6	0.0, 77.8	0.0, 88.9	-55.6, 55.6
		Mean Diff (95% CI) [a]			-4.5 (-13.0, 3.9)			-2.2 (-18.5, 14.1)
		P-value [a]			0.284			0.774
		Mean Diff (95% CI) [b]			-2.3 (-18.3, 13.7)			
		P-value [b]			0.775			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.12)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	30.0	29.0	-1.0	38.9	31.5	-7.4
		SD	23.15	21.14	21.22	24.39	30.27	32.60
		Median	33.3	33.3	0.0	33.3	27.8	-11.1
		95% CI	21.8, 38.2	21.5, 36.5	-8.5, 6.5	23.4, 54.4	12.2, 50.7	-28.1, 13.3
		Q1, Q3	11.1, 44.4	11.1, 44.4	-11.1, 11.1	22.2, 61.1	5.6, 44.4	-22.2, 11.1
		Min, Max	0.0, 77.8	0.0, 77.8	-44.4, 33.3	0.0, 77.8	0.0, 100.0	-77.8, 44.4
		Mean Diff (95% CI) [a]			-1.0 (-8.5, 6.5)			-7.4 (-28.1, 13.3)
		P-value [a]			0.786			0.448
		Mean Diff (95% CI) [b]			6.4 (-10.4, 23.1)			
		P-value [b]			0.445			
		Effect Size (95% CI) [c]			0.27 (0.05, 0.48)			
	C15D1	N	28	28	28	13	13	13
		Mean	33.3	31.7	-1.6	38.5	39.3	0.9
		SD	22.83	25.07	22.97	23.40	22.51	21.97
		Median	33.3	27.8	0.0	33.3	33.3	0.0
		95% CI	24.5, 42.2	22.0, 41.5	-10.5, 7.3	24.3, 52.6	25.7, 52.9	-12.4, 14.1
		Q1, Q3	16.7, 55.6	22.2, 44.4	-16.7, 11.1	33.3, 55.6	22.2, 55.6	-11.1, 22.2
		Min, Max	0.0, 77.8	0.0, 100.0	-44.4, 44.4	0.0, 77.8	11.1, 77.8	-33.3, 33.3
		Mean Diff (95% CI) [a]			-1.6 (-10.5, 7.3)			0.9 (-12.4, 14.1)
		P-value [a]			0.718			0.891
		Mean Diff (95% CI) [b]			-2.4 (-17.8, 12.9)			
		P-value [b]			0.750			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.11)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	30.2	27.8	-2.4	37.8	32.2	-5.6
		SD	22.80	22.53	24.82	21.72	21.24	20.45
		Median	27.8	33.3	0.0	33.3	33.3	-5.6
		95% CI	21.3, 39.0	19.0, 36.5	-12.0, 7.2	22.2, 53.3	17.0, 47.4	-20.2, 9.1
		Q1, Q3	11.1, 44.4	0.0, 38.9	-16.7, 5.6	33.3, 55.6	22.2, 44.4	-22.2, 11.1
		Min, Max	0.0, 77.8	0.0, 66.7	-55.6, 44.4	0.0, 66.7	0.0, 77.8	-33.3, 22.2
		Mean Diff (95% CI) [a]			-2.4 (-12.0, 7.2)			-5.6 (-20.2, 9.1)
		P-value [a]			0.616			0.413
		Mean Diff (95% CI) [b]			3.2 (-14.6, 21.0)			
		P-value [b]			0.719			
		Effect Size (95% CI) [c]			0.13 (-0.08, 0.34)			
	C17D1	N	26	26	26	7	7	7
		Mean	32.1	25.6	-6.4	42.9	38.1	-4.8
		SD	22.52	21.95	22.92	23.51	26.34	16.80
		Median	33.3	22.2	-5.6	44.4	33.3	0.0
		95% CI	23.0, 41.1	16.8, 34.5	-15.7, 2.8	21.1, 64.6	13.7, 62.5	-20.3, 10.8
		Q1, Q3	22.2, 44.4	11.1, 33.3	-22.2, 0.0	33.3, 66.7	22.2, 66.7	-11.1, 0.0
		Min, Max	0.0, 77.8	0.0, 66.7	-55.6, 44.4	0.0, 66.7	0.0, 77.8	-33.3, 22.2
		Mean Diff (95% CI) [a]			-6.4 (-15.7, 2.8)			-4.8 (-20.3, 10.8)
		P-value [a]			0.166			0.482
		Mean Diff (95% CI) [b]			-1.6 (-20.6, 17.3)			
		P-value [b]			0.861			
		Effect Size (95% CI) [c]			-0.07 (-0.28, 0.14)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	34.3	26.3	-8.1	34.9	31.7	-3.2
		SD	23.23	24.38	25.01	23.51	28.28	19.99
		Median	33.3	22.2	-11.1	33.3	33.3	-11.1
		95% CI	24.0, 44.6	15.5, 37.1	-19.2, 3.0	13.2, 56.7	5.6, 57.9	-21.7, 15.3
		Q1, Q3	22.2, 55.6	0.0, 44.4	-22.2, 0.0	11.1, 55.6	0.0, 55.6	-11.1, 22.2
		Min, Max	0.0, 77.8	0.0, 88.9	-55.6, 66.7	0.0, 66.7	0.0, 77.8	-33.3, 22.2
		Mean Diff (95% CI) [a]			-8.1 (-19.2, 3.0)			-3.2 (-21.7, 15.3)
		P-value [a]			0.144			0.689
		Mean Diff (95% CI) [b]			-4.9 (-26.3, 16.4)			
		P-value [b]			0.641			
		Effect Size (95% CI) [c]			-0.20 (-0.42, 0.01)			
	C19D1	N	20	20	20	6	6	6
		Mean	33.9	25.0	-8.9	31.5	38.9	7.4
		SD	24.31	20.67	22.40	23.74	13.61	20.69
		Median	33.3	27.8	0.0	33.3	33.3	5.6
		95% CI	22.5, 45.3	15.3, 34.7	-19.4, 1.6	6.6, 56.4	24.6, 53.2	-14.3, 29.1
		Q1, Q3	16.7, 55.6	11.1, 33.3	-22.2, 5.6	11.1, 44.4	33.3, 55.6	-11.1, 22.2
		Min, Max	0.0, 77.8	0.0, 77.8	-55.6, 22.2	0.0, 66.7	22.2, 55.6	-11.1, 33.3
		Mean Diff (95% CI) [a]			-8.9 (-19.4, 1.6)			7.4 (-14.3, 29.1)
		P-value [a]			0.092			0.421
		Mean Diff (95% CI) [b]			-16.3 (-37.5, 4.9)			
		P-value [b]			0.125			
		Effect Size (95% CI) [c]			-0.68 (-0.90, -0.46)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	30.6	26.7	-3.9	36.1	36.1	0.0
		SD	26.21	18.52	18.12	27.78	13.98	15.71
		Median	27.8	27.8	0.0	38.9	33.3	-5.6
		95% CI	18.3, 42.8	18.0, 35.3	-12.4, 4.6	-8.1, 80.3	13.9, 58.4	-25.0, 25.0
		Q1, Q3	5.6, 55.6	22.2, 33.3	-11.1, 0.0	16.7, 55.6	27.8, 44.4	-11.1, 11.1
		Min, Max	0.0, 77.8	0.0, 77.8	-33.3, 33.3	0.0, 66.7	22.2, 55.6	-11.1, 22.2
		Mean Diff (95% CI) [a]			-3.9 (-12.4, 4.6)			0.0 (-25.0, 25.0)
		P-value [a]			0.349			1.000
		Mean Diff (95% CI) [b]			-3.9 (-24.1, 16.3)			
		P-value [b]			0.694			
		Effect Size (95% CI) [c]			-0.16 (-0.37, 0.05)			
	C21D1	N	18	18	18	4	4	4
		Mean	34.0	24.7	-9.3	36.1	30.6	-5.6
		SD	25.42	22.08	25.64	27.78	13.98	21.28
		Median	33.3	22.2	-5.6	38.9	33.3	0.0
		95% CI	21.3, 46.6	13.7, 35.7	-22.0, 3.5	-8.1, 80.3	8.3, 52.8	-39.4, 28.3
		Q1, Q3	11.1, 55.6	0.0, 33.3	-22.2, 0.0	16.7, 55.6	22.2, 38.9	-22.2, 11.1
		Min, Max	0.0, 77.8	0.0, 77.8	-55.6, 44.4	0.0, 66.7	11.1, 44.4	-33.3, 11.1
		Mean Diff (95% CI) [a]			-9.3 (-22.0, 3.5)			-5.6 (-39.4, 28.3)
		P-value [a]			0.144			0.638
		Mean Diff (95% CI) [b]			-3.7 (-32.6, 25.2)			
		P-value [b]			0.792			
		Effect Size (95% CI) [c]			-0.15 (-0.37, 0.06)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	32.6	28.1	-4.4	37.0	22.2	-14.8
		SD	24.29	19.64	19.61	33.95	19.25	16.97
		Median	33.3	22.2	0.0	44.4	33.3	-11.1
		95% CI	19.1, 46.0	17.3, 39.0	-15.3, 6.4	-47.3, 121.4	-25.6, 70.0	-57.0, 27.3
		Q1, Q3	11.1, 55.6	22.2, 33.3	-22.2, 0.0	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 77.8	0.0, 77.8	-33.3, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			-4.4 (-15.3, 6.4)			-14.8 (-57.0, 27.3)
		P-value [a]			0.395			0.270
		Mean Diff (95% CI) [b]			10.4 (-15.5, 36.2)			
		P-value [b]			0.408			
		Effect Size (95% CI) [c]			0.43 (0.22, 0.65)			
	C23D1	N	11	11	11	3	3	3
		Mean	35.4	32.3	-3.0	37.0	25.9	-11.1
		SD	27.59	18.23	22.27	33.95	23.13	11.11
		Median	33.3	33.3	-11.1	44.4	33.3	-11.1
		95% CI	16.8, 53.9	20.1, 44.6	-18.0, 11.9	-47.3, 121.4	-31.5, 83.4	-38.7, 16.5
		Q1, Q3	11.1, 66.7	22.2, 44.4	-22.2, 11.1	0.0, 66.7	0.0, 44.4	-22.2, 0.0
		Min, Max	0.0, 77.8	0.0, 66.7	-33.3, 44.4	0.0, 66.7	0.0, 44.4	-22.2, 0.0
		Mean Diff (95% CI) [a]			-3.0 (-18.0, 11.9)			-11.1 (-38.7, 16.5)
		P-value [a]			0.661			0.225
		Mean Diff (95% CI) [b]			8.1 (-21.5, 37.6)			
		P-value [b]			0.563			
		Effect Size (95% CI) [c]			0.34 (0.12, 0.55)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	33.3	31.1	-2.2	33.3	27.8	-5.6
		SD	28.21	17.21	20.82	47.14	39.28	7.86
		Median	27.8	33.3	0.0	33.3	27.8	-5.6
		95% CI	13.2, 53.5	18.8, 43.4	-17.1, 12.7	-390.2, 456.9	-325.2, 380.7	-76.1, 65.0
		Q1, Q3	11.1, 66.7	22.2, 33.3	-11.1, 0.0	0.0, 66.7	0.0, 55.6	-11.1, 0.0
		Min, Max	0.0, 77.8	0.0, 66.7	-33.3, 33.3	0.0, 66.7	0.0, 55.6	-11.1, 0.0
		Mean Diff (95% CI) [a]			-2.2 (-17.1, 12.7)			-5.6 (-76.1, 65.0)
		P-value [a]			0.743			0.500
		Mean Diff (95% CI) [b]			3.3 (-31.0, 37.7)			
		P-value [b]			0.833			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.35)			
	C25D1	N	9	9	9	0	0	0
		Mean	37.0	33.3	-3.7	NE	NE	NE
		SD	27.22	26.06	26.64	NE	NE	NE
		Median	33.3	33.3	0.0	NE	NE	NE
		95% CI	16.1, 58.0	13.3, 53.4	-24.2, 16.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	22.2, 66.7	22.2, 33.3	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 77.8	0.0, 77.8	-33.3, 55.6	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-3.7 (-24.2, 16.8)			NE (NE, NE)
		P-value [a]			0.688			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	23.6	27.8	4.2	0.0	0.0	0.0
		SD	21.77	24.49	27.18	NE	NE	NE
		Median	22.2	22.2	0.0	0.0	0.0	0.0
		95% CI	5.4, 41.8	7.3, 48.3	-18.6, 26.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	5.6, 33.3	11.1, 38.9	-11.1, 5.6	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 77.8	-22.2, 66.7	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			4.2 (-18.6, 26.9)			0.0 (NE, NE)
		P-value [a]			0.678			NE
		Mean Diff (95% CI) [b]			4.2 (-64.0, 72.3)			
		P-value [b]			0.889			
		Effect Size (95% CI) [c]			0.17 (-0.04, 0.39)			
	C27D1	N	8	8	8	1	1	1
		Mean	23.6	22.2	-1.4	0.0	0.0	0.0
		SD	21.77	21.41	26.85	NE	NE	NE
		Median	22.2	22.2	-5.6	0.0	0.0	0.0
		95% CI	5.4, 41.8	4.3, 40.1	-23.8, 21.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	5.6, 33.3	5.6, 27.8	-16.7, 5.6	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 55.6	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-1.4 (-23.8, 21.1)			0.0 (NE, NE)
		P-value [a]			0.888			NE
		Mean Diff (95% CI) [b]			-1.4 (-68.7, 66.0)			
		P-value [b]			0.962			
		Effect Size (95% CI) [c]			-0.06 (-0.27, 0.15)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	22.2	22.2	0.0	0.0	0.0	0.0
		SD	23.13	20.29	24.85	NE	NE	NE
		Median	22.2	22.2	0.0	0.0	0.0	0.0
		95% CI	0.8, 43.6	3.5, 41.0	-23.0, 23.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	-22.2, 11.1	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 55.6	-33.3, 44.4	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (-23.0, 23.0)			0.0 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			0.0 (-65.0, 65.0)			
		P-value [b]			1.000			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
	C29D1	N	4	4	4	1	1	1
		Mean	33.3	38.9	5.6	0.0	55.6	55.6
		SD	24.00	36.85	50.10	NE	NE	NE
		Median	27.8	33.3	-11.1	0.0	55.6	55.6
		95% CI	-4.9, 71.5	-19.7, 97.5	-74.2, 85.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	16.7, 50.0	16.7, 61.1	-27.8, 38.9	0.0, 0.0	55.6, 55.6	55.6, 55.6
		Min, Max	11.1, 66.7	0.0, 88.9	-33.3, 77.8	0.0, 0.0	55.6, 55.6	55.6, 55.6
		Mean Diff (95% CI) [a]			5.6 (-74.2, 85.3)			55.6 (NE, NE)
		P-value [a]			0.839			NE
		Mean Diff (95% CI) [b]			-50.0 (-228.3, 128.3)			
		P-value [b]			0.438			
		Effect Size (95% CI) [c]			-2.08 (-2.34, -1.81)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	16.7	25.0	8.3	0.0	44.4	44.4
		SD	14.34	31.91	33.18	NE	NE	NE
		Median	16.7	16.7	0.0	0.0	44.4	44.4
		95% CI	-6.2, 39.5	-25.8, 75.8	-44.5, 61.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	5.6, 27.8	0.0, 50.0	-11.1, 27.8	0.0, 0.0	44.4, 44.4	44.4, 44.4
		Min, Max	0.0, 33.3	0.0, 66.7	-22.2, 55.6	0.0, 0.0	44.4, 44.4	44.4, 44.4
		Mean Diff (95% CI) [a]			8.3 (-44.5, 61.1)			44.4 (NE, NE)
		P-value [a]			0.650			NE
		Mean Diff (95% CI) [b]			-36.1 (-154.2, 81.9)			
		P-value [b]			0.402			
		Effect Size (95% CI) [c]			-1.50 (-1.74, -1.26)			
	C31D1	N	2	2	2	1	1	1
		Mean	27.8	11.1	-16.7	0.0	33.3	33.3
		SD	7.86	15.71	7.86	NE	NE	NE
		Median	27.8	11.1	-16.7	0.0	33.3	33.3
		95% CI	-42.8, 98.4	-130.1, 152.3	-87.3, 53.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	22.2, 33.3	0.0, 22.2	-22.2, -11.1	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	22.2, 33.3	0.0, 22.2	-22.2, -11.1	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			-16.7 (-87.3, 53.9)			33.3 (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			-50.0 (-172.3, 72.3)			
		P-value [b]			0.121			
		Effect Size (95% CI) [c]			-2.08 (-2.34, -1.81)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	27.8	11.1	-16.7	0.0	33.3	33.3
		SD	7.86	15.71	7.86	NE	NE	NE
		Median	27.8	11.1	-16.7	0.0	33.3	33.3
		95% CI	-42.8, 98.4	-130.1, 152.3	-87.3, 53.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	22.2, 33.3	0.0, 22.2	-22.2, -11.1	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	22.2, 33.3	0.0, 22.2	-22.2, -11.1	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			-16.7 (-87.3, 53.9)			33.3 (NE, NE)
		P-value [a]			0.205			NE
		Mean Diff (95% CI) [b]			-50.0 (-172.3, 72.3)			
		P-value [b]			0.121			
		Effect Size (95% CI) [c]			-2.08 (-2.34, -1.81)			
	C33D1	N	3	3	3	1	1	1
		Mean	18.5	18.5	0.0	0.0	33.3	33.3
		SD	16.97	12.83	11.11	NE	NE	NE
		Median	22.2	11.1	0.0	0.0	33.3	33.3
		95% CI	-23.6, 60.7	-13.4, 50.4	-27.6, 27.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	11.1, 33.3	-11.1, 11.1	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 33.3	11.1, 33.3	-11.1, 11.1	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (-27.6, 27.6)			33.3 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			-33.3 (-88.5, 21.9)			
		P-value [b]			0.122			
		Effect Size (95% CI) [c]			-1.39 (-1.62, -1.15)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	18.5	14.8	-3.7	NE	NE	NE
		SD	16.97	25.66	16.97	NE	NE	NE
		Median	22.2	0.0	0.0	NE	NE	NE
		95% CI	-23.6, 60.7	-48.9, 78.6	-45.9, 38.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 44.4	-22.2, 11.1	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 33.3	0.0, 44.4	-22.2, 11.1	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-3.7 (-45.9, 38.5)			NE (NE, NE)
		P-value [a]			0.742			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	27.8	16.7	-11.1	NE	NE	NE
		SD	7.86	23.57	15.71	NE	NE	NE
		Median	27.8	16.7	-11.1	NE	NE	NE
		95% CI	-42.8, 98.4	-195.1, 228.4	-152.3, 130.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	22.2, 33.3	0.0, 33.3	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	22.2, 33.3	0.0, 33.3	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-11.1 (-152.3, 130.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	18.5	11.1	-7.4	NE	NE	NE
		SD	16.97	19.25	12.83	NE	NE	NE
		Median	22.2	0.0	0.0	NE	NE	NE
		95% CI	-23.6, 60.7	-36.7, 58.9	-39.3, 24.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 33.3	0.0, 33.3	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-7.4 (-39.3, 24.5)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	18.5	11.1	-7.4	NE	NE	NE
		SD	16.97	19.25	12.83	NE	NE	NE
		Median	22.2	0.0	0.0	NE	NE	NE
		95% CI	-23.6, 60.7	-36.7, 58.9	-39.3, 24.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 33.3	0.0, 33.3	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-7.4 (-39.3, 24.5)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	11.1	0.0	-11.1	NE	NE	NE
		SD	15.71	0.00	15.71	NE	NE	NE
		Median	11.1	0.0	-11.1	NE	NE	NE
		95% CI	-130.1, 152.3	0.0, 0.0	-152.3, 130.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 22.2	0.0, 0.0	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 22.2	0.0, 0.0	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-11.1 (-152.3, 130.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	11.1	0.0	-11.1	NE	NE	NE
		SD	15.71	0.00	15.71	NE	NE	NE
		Median	11.1	0.0	-11.1	NE	NE	NE
		95% CI	-130.1, 152.3	0.0, 0.0	-152.3, 130.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 22.2	0.0, 0.0	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 22.2	0.0, 0.0	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-11.1 (-152.3, 130.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	11.1	0.0	-11.1	NE	NE	NE
		SD	15.71	0.00	15.71	NE	NE	NE
		Median	11.1	0.0	-11.1	NE	NE	NE
		95% CI	-130.1, 152.3	0.0, 0.0	-152.3, 130.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 22.2	0.0, 0.0	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 22.2	0.0, 0.0	-22.2, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-11.1 (-152.3, 130.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	11.1	11.1	0.0	NE	NE	NE
		SD	15.71	15.71	0.00	NE	NE	NE
		Median	11.1	11.1	0.0	NE	NE	NE
		95% CI	-130.1, 152.3	-130.1, 152.3	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 22.2	0.0, 22.2	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 22.2	0.0, 22.2	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	22.2	22.2	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	22.2	22.2	0.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	22.2, 22.2	22.2, 22.2	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	22.2, 22.2	22.2, 22.2	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	22.2	33.3	11.1	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	22.2	33.3	11.1	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	22.2, 22.2	33.3, 33.3	11.1, 11.1	NE, NE	NE, NE	NE, NE
		Min, Max	22.2, 22.2	33.3, 33.3	11.1, 11.1	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	126	126	126
		Mean	34.2	42.0	7.8	33.3	40.5	7.2
		SD	24.25	31.80	27.38	23.85	28.21	23.30
		Median	33.3	33.3	0.0	33.3	33.3	11.1
		95% CI	30.0, 38.4	36.5, 47.5	3.1, 12.5	29.1, 37.5	35.5, 45.5	3.1, 11.3
		Q1, Q3	22.2, 44.4	11.1, 66.7	-11.1, 22.2	11.1, 44.4	22.2, 55.6	0.0, 22.2
		Min, Max	0.0, 100.0	0.0, 100.0	-77.8, 77.8	0.0, 100.0	0.0, 100.0	-66.7, 77.8
		Mean Diff (95% CI) [a]			7.8 (3.1, 12.5)			7.2 (3.1, 11.3)
		P-value [a]			0.001			0.001
		Mean Diff (95% CI) [b]			0.6 (-5.6, 6.9)			
		P-value [b]			0.846			
		Effect Size (95% CI) [c]			0.03 (-0.19, 0.24)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	26.2	34.9	8.7	25.9	51.9	25.9
		SD	17.76	21.73	21.87	19.25	31.91	26.64
		Median	22.2	33.3	11.1	22.2	44.4	11.1
		95% CI	15.9, 36.4	22.4, 47.5	-3.9, 21.4	11.1, 40.7	27.3, 76.4	5.4, 46.4
		Q1, Q3	11.1, 33.3	22.2, 44.4	-11.1, 22.2	11.1, 33.3	33.3, 66.7	11.1, 33.3
		Min, Max	0.0, 55.6	0.0, 77.8	-22.2, 44.4	0.0, 66.7	11.1, 100.0	0.0, 88.9
		Mean Diff (95% CI) [a]			8.7 (-3.9, 21.4)			25.9 (5.4, 46.4)
		P-value [a]			0.159			0.019
		Mean Diff (95% CI) [b]			-17.2 (-38.3, 4.0)			
		P-value [b]			0.106			
		Effect Size (95% CI) [c]			-0.71 (-0.93, -0.50)			
Nausea and Vomiting	Baseline	N	174			165		
		Mean	8.4			8.7		
		SD	16.59			16.73		
		Median	0.0			0.0		
		95% CI	5.9, 10.9			6.1, 11.3		
		Q1, Q3	0.0, 16.7			0.0, 16.7		
		Min, Max	0.0, 100.0			0.0, 83.3		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	8.6	13.0	4.5	8.7	10.4	1.7
		SD	16.94	16.15	14.85	16.95	16.12	17.38
		95% CI	5.8, 11.3	10.5, 15.6	2.1, 6.9	5.9, 11.5	7.8, 13.1	-1.1, 4.6
		Median	0.0	16.7	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 8.3
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 50.0	0.0, 83.3	0.0, 83.3	-66.7, 50.0
		Mean Diff (95% CI) [a]			4.5 (2.1, 6.9)			1.7 (-1.1, 4.6)
		P-value [a]			<.001			0.233
		Mean Diff (95% CI) [b]			2.8 (-0.9, 6.5)			
		P-value [b]			0.142			
		Effect Size (95% CI) [c]			0.17 (-0.05, 0.38)			
	C3D1	N	124	124	124	101	101	101
		Mean	7.8	10.9	3.1	7.3	8.4	1.2
		SD	16.66	16.87	21.08	14.80	16.60	16.20
		95% CI	4.8, 10.8	7.9, 13.9	-0.7, 6.8	4.3, 10.2	5.1, 11.7	-2.0, 4.4
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 83.3	-100.0, 66.7	0.0, 66.7	0.0, 83.3	-66.7, 66.7
		Mean Diff (95% CI) [a]			3.1 (-0.7, 6.8)			1.2 (-2.0, 4.4)
		P-value [a]			0.105			0.475
		Mean Diff (95% CI) [b]			1.9 (-3.1, 7.0)			
		P-value [b]			0.449			
		Effect Size (95% CI) [c]			0.12 (-0.10, 0.33)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	8.6	10.3	1.6	8.2	6.7	-1.4
		SD	17.47	13.84	16.74	17.06	13.68	18.23
		95% CI	5.4, 11.9	7.7, 12.9	-1.5, 4.8	4.7, 11.7	3.9, 9.5	-5.2, 2.3
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-83.3, 50.0	0.0, 83.3	0.0, 83.3	-66.7, 50.0
		Mean Diff (95% CI) [a]			1.6 (-1.5, 4.8)			-1.4 (-5.2, 2.3)
		P-value [a]			0.303			0.453
		Mean Diff (95% CI) [b]			3.1 (-1.8, 7.9)			
		P-value [b]			0.212			
		Effect Size (95% CI) [c]			0.18 (-0.03, 0.40)			
	C5D1	N	96	96	96	80	80	80
		Mean	7.3	8.5	1.2	7.7	6.3	-1.5
		SD	15.07	15.29	18.14	16.76	12.26	17.63
		95% CI	4.2, 10.3	5.4, 11.6	-2.5, 4.9	4.0, 11.4	3.5, 9.0	-5.4, 2.5
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 83.3	0.0, 66.7	-66.7, 66.7
		Mean Diff (95% CI) [a]			1.2 (-2.5, 4.9)			-1.5 (-5.4, 2.5)
		P-value [a]			0.513			0.462
		Mean Diff (95% CI) [b]			2.7 (-2.7, 8.0)			
		P-value [b]			0.325			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	69	69	69
		Mean	6.9	7.6	0.7	7.5	6.3	-1.2
		SD	14.84	10.79	13.66	16.30	14.03	14.66
		95% CI	3.9, 10.0	5.5, 9.8	-2.1, 3.5	3.6, 11.4	2.9, 9.7	-4.7, 2.3
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 33.3	-66.7, 33.3	0.0, 83.3	0.0, 83.3	-66.7, 33.3
		Mean Diff (95% CI) [a]			0.7 (-2.1, 3.5)			-1.2 (-4.7, 2.3)
		P-value [a]			0.620			0.496
		Mean Diff (95% CI) [b]			1.9 (-2.5, 6.3)			
		P-value [b]			0.394			
		Effect Size (95% CI) [c]			0.11 (-0.10, 0.33)			
	C7D1	N	79	79	79	53	53	53
		Mean	7.8	5.9	-1.9	6.9	5.0	-1.9
		SD	16.84	10.35	18.49	14.41	11.60	13.34
		95% CI	4.0, 11.6	3.6, 8.2	-6.0, 2.2	2.9, 10.9	1.8, 8.2	-5.6, 1.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 50.0	-100.0, 33.3	0.0, 66.7	0.0, 50.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			-1.9 (-6.0, 2.2)			-1.9 (-5.6, 1.8)
		P-value [a]			0.364			0.308
		Mean Diff (95% CI) [b]			0.0 (-5.9, 5.8)			
		P-value [b]			0.997			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	8.3	7.0	-1.3	7.3	4.0	-3.3
		SD	17.32	10.98	16.05	14.74	10.41	13.04
		95% CI	4.4, 12.3	4.5, 9.5	-5.0, 2.4	3.1, 11.5	1.0, 7.0	-7.0, 0.4
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 33.3	-66.7, 33.3	0.0, 66.7	0.0, 50.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			-1.3 (-5.0, 2.4)			-3.3 (-7.0, 0.4)
		P-value [a]			0.477			0.077
		Mean Diff (95% CI) [b]			2.0 (-3.4, 7.4)			
		P-value [b]			0.459			
		Effect Size (95% CI) [c]			0.12 (-0.09, 0.33)			
	C9D1	N	60	60	60	42	42	42
		Mean	9.2	7.5	-1.7	6.7	4.0	-2.8
		SD	18.52	16.07	20.29	15.64	9.61	14.22
		95% CI	4.4, 14.0	3.3, 11.7	-6.9, 3.6	1.9, 11.6	1.0, 7.0	-7.2, 1.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 83.3	0.0, 66.7	0.0, 50.0	-50.0, 16.7
		Mean Diff (95% CI) [a]			-1.7 (-6.9, 3.6)			-2.8 (-7.2, 1.7)
		P-value [a]			0.527			0.213
		Mean Diff (95% CI) [b]			1.1 (-6.1, 8.3)			
		P-value [b]			0.760			
		Effect Size (95% CI) [c]			0.07 (-0.15, 0.28)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	7.7	6.2	-1.5	8.3	5.0	-3.3
		SD	17.65	11.35	14.93	17.37	13.94	11.91
		95% CI	2.9, 12.5	3.1, 9.3	-5.6, 2.5	1.8, 14.8	-0.2, 10.2	-7.8, 1.1
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 33.3	-66.7, 33.3	0.0, 66.7	0.0, 66.7	-50.0, 16.7
		Mean Diff (95% CI) [a]			-1.5 (-5.6, 2.5)			-3.3 (-7.8, 1.1)
		P-value [a]			0.451			0.136
		Mean Diff (95% CI) [b]			1.8 (-4.5, 8.1)			
		P-value [b]			0.574			
		Effect Size (95% CI) [c]			0.11 (-0.11, 0.32)			
	C11D1	N	45	45	45	23	23	23
		Mean	7.8	9.6	1.9	6.5	1.4	-5.1
		SD	18.67	18.63	20.48	14.86	4.80	15.44
		95% CI	2.2, 13.4	4.0, 15.2	-4.3, 8.0	0.1, 12.9	-0.6, 3.5	-11.7, 1.6
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 66.7	0.0, 16.7	-66.7, 16.7
		Mean Diff (95% CI) [a]			1.9 (-4.3, 8.0)			-5.1 (-11.7, 1.6)
		P-value [a]			0.547			0.129
		Mean Diff (95% CI) [b]			6.9 (-2.8, 16.6)			
		P-value [b]			0.159			
		Effect Size (95% CI) [c]			0.41 (0.20, 0.63)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	8.5	9.8	1.2	5.3	1.8	-3.5
		SD	19.41	16.23	18.41	9.71	5.26	10.51
		95% CI	2.4, 14.7	4.6, 14.9	-4.6, 7.0	0.6, 9.9	-0.8, 4.3	-8.6, 1.6
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-66.7, 66.7	0.0, 33.3	0.0, 16.7	-33.3, 16.7
		Mean Diff (95% CI) [a]			1.2 (-4.6, 7.0)			-3.5 (-8.6, 1.6)
		P-value [a]			0.674			0.163
		Mean Diff (95% CI) [b]			4.7 (-4.4, 13.8)			
		P-value [b]			0.302			
		Effect Size (95% CI) [c]			0.28 (0.07, 0.50)			
	C13D1	N	32	32	32	15	15	15
		Mean	7.3	10.4	3.1	4.4	2.2	-2.2
		SD	14.00	21.48	21.77	9.89	5.86	10.67
		95% CI	2.2, 12.3	2.7, 18.2	-4.7, 11.0	-1.0, 9.9	-1.0, 5.5	-8.1, 3.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 8.3	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 50.0	0.0, 100.0	-33.3, 100.0	0.0, 33.3	0.0, 16.7	-33.3, 16.7
		Mean Diff (95% CI) [a]			3.1 (-4.7, 11.0)			-2.2 (-8.1, 3.7)
		P-value [a]			0.423			0.433
		Mean Diff (95% CI) [b]			5.3 (-6.6, 17.3)			
		P-value [b]			0.374			
		Effect Size (95% CI) [c]			0.32 (0.11, 0.53)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	7.1	6.6	-0.5	2.8	5.6	2.8
		SD	13.84	14.40	11.40	6.49	8.21	9.62
		95% CI	2.2, 12.0	1.5, 11.7	-4.5, 3.5	-1.3, 6.9	0.3, 10.8	-3.3, 8.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 8.3
		Min, Max	0.0, 50.0	0.0, 66.7	-33.3, 33.3	0.0, 16.7	0.0, 16.7	-16.7, 16.7
		Mean Diff (95% CI) [a]			-0.5 (-4.5, 3.5)			2.8 (-3.3, 8.9)
		P-value [a]			0.801			0.339
		Mean Diff (95% CI) [b]			-3.3 (-10.7, 4.2)			
		P-value [b]			0.380			
		Effect Size (95% CI) [c]			-0.20 (-0.41, 0.02)			
	C15D1	N	28	28	28	13	13	13
		Mean	8.3	6.5	-1.8	5.1	1.3	-3.8
		SD	14.70	17.18	11.42	10.51	4.62	9.99
		95% CI	2.6, 14.0	-0.1, 13.2	-6.2, 2.6	-1.2, 11.5	-1.5, 4.1	-9.9, 2.2
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 50.0	0.0, 83.3	-33.3, 33.3	0.0, 33.3	0.0, 16.7	-33.3, 0.0
		Mean Diff (95% CI) [a]			-1.8 (-6.2, 2.6)			-3.8 (-9.9, 2.2)
		P-value [a]			0.415			0.190
		Mean Diff (95% CI) [b]			2.1 (-5.4, 9.5)			
		P-value [b]			0.580			
		Effect Size (95% CI) [c]			0.12 (-0.09, 0.34)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	7.7	10.1	2.4	5.0	8.3	3.3
		SD	14.69	14.59	14.14	11.25	14.16	17.21
		95% CI	2.0, 13.4	4.5, 15.8	-3.1, 7.9	-3.0, 13.0	-1.8, 18.5	-9.0, 15.6
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 8.3	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 16.7
		Min, Max	0.0, 50.0	0.0, 50.0	-16.7, 50.0	0.0, 33.3	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			2.4 (-3.1, 7.9)			3.3 (-9.0, 15.6)
		P-value [a]			0.381			0.555
		Mean Diff (95% CI) [b]			-1.0 (-12.1, 10.2)			
		P-value [b]			0.864			
		Effect Size (95% CI) [c]			-0.06 (-0.27, 0.16)			
	C17D1	N	26	26	26	7	7	7
		Mean	8.3	9.0	0.6	2.4	0.0	-2.4
		SD	15.09	15.80	13.73	6.30	0.00	6.30
		95% CI	2.2, 14.4	2.6, 15.4	-4.9, 6.2	-3.4, 8.2	0.0, 0.0	-8.2, 3.4
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 50.0	0.0, 50.0	-33.3, 50.0	0.0, 16.7	0.0, 0.0	-16.7, 0.0
		Mean Diff (95% CI) [a]			0.6 (-4.9, 6.2)			-2.4 (-8.2, 3.4)
		P-value [a]			0.814			0.356
		Mean Diff (95% CI) [b]			3.0 (-8.0, 14.0)			
		P-value [b]			0.578			
		Effect Size (95% CI) [c]			0.18 (-0.03, 0.39)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	7.6	5.3	-2.3	2.4	2.4	0.0
		SD	13.34	9.47	12.91	6.30	6.30	9.62
		95% CI	1.7, 13.5	1.1, 9.5	-8.0, 3.4	-3.4, 8.2	-3.4, 8.2	-8.9, 8.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 16.7	0.0, 16.7	-16.7, 16.7
		Mean Diff (95% CI) [a]			-2.3 (-8.0, 3.4)			0.0 (-8.9, 8.9)
		P-value [a]			0.418			1.000
		Mean Diff (95% CI) [b]			-2.3 (-13.2, 8.6)			
		P-value [b]			0.672			
		Effect Size (95% CI) [c]			-0.14 (-0.35, 0.08)			
	C19D1	N	20	20	20	6	6	6
		Mean	8.3	4.2	-4.2	2.8	5.6	2.8
		SD	13.79	10.64	15.17	6.80	8.61	6.80
		95% CI	1.9, 14.8	-0.8, 9.1	-11.3, 2.9	-4.4, 9.9	-3.5, 14.6	-4.4, 9.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 16.7	0.0, 16.7	0.0, 16.7
		Mean Diff (95% CI) [a]			-4.2 (-11.3, 2.9)			2.8 (-4.4, 9.9)
		P-value [a]			0.234			0.363
		Mean Diff (95% CI) [b]			-6.9 (-20.3, 6.4)			
		P-value [b]			0.292			
		Effect Size (95% CI) [c]			-0.42 (-0.63, -0.20)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	6.7	5.8	-0.8	4.2	4.2	0.0
		SD	12.57	11.18	11.44	8.33	8.33	0.00
		95% CI	0.8, 12.5	0.6, 11.1	-6.2, 4.5	-9.1, 17.4	-9.1, 17.4	0.0, 0.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 8.3	0.0, 8.3	0.0, 0.0	0.0, 8.3	0.0, 8.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-16.7, 33.3	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Mean Diff (95% CI) [a]			-0.8 (-6.2, 4.5)			0.0 (0.0, 0.0)
		P-value [a]			0.748			NE
		Mean Diff (95% CI) [b]			-0.8 (-12.9, 11.2)			
		P-value [b]			0.887			
		Effect Size (95% CI) [c]			-0.05 (-0.26, 0.16)			
	C21D1	N	18	18	18	4	4	4
		Mean	7.4	2.8	-4.6	4.2	8.3	4.2
		SD	13.06	6.39	9.58	8.33	9.62	8.33
		95% CI	0.9, 13.9	-0.4, 6.0	-9.4, 0.1	-9.1, 17.4	-7.0, 23.6	-9.1, 17.4
		Median	0.0	0.0	0.0	0.0	8.3	0.0
		Q1, Q3	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 8.3	0.0, 16.7	0.0, 8.3
		Min, Max	0.0, 33.3	0.0, 16.7	-33.3, 0.0	0.0, 16.7	0.0, 16.7	0.0, 16.7
		Mean Diff (95% CI) [a]			-4.6 (-9.4, 0.1)			4.2 (-9.1, 17.4)
		P-value [a]			0.056			0.391
		Mean Diff (95% CI) [b]			-8.8 (-19.6, 2.0)			
		P-value [b]			0.106			
		Effect Size (95% CI) [c]			-0.53 (-0.74, -0.31)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	6.7	4.4	-2.2	5.6	5.6	0.0
		SD	12.28	7.63	8.61	9.62	9.62	0.00
		95% CI	-0.1, 13.5	0.2, 8.7	-7.0, 2.5	-18.3, 29.5	-18.3, 29.5	0.0, 0.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 16.7	-16.7, 16.7	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Mean Diff (95% CI) [a]			-2.2 (-7.0, 2.5)			0.0 (0.0, 0.0)
		P-value [a]			0.334			NE
		Mean Diff (95% CI) [b]			-2.2 (-13.0, 8.6)			
		P-value [b]			0.668			
		Effect Size (95% CI) [c]			-0.13 (-0.35, 0.08)			
	C23D1	N	11	11	11	3	3	3
		Mean	6.1	9.1	3.0	5.6	5.6	0.0
		SD	11.24	20.23	16.36	9.62	9.62	0.00
		95% CI	-1.5, 13.6	-4.5, 22.7	-8.0, 14.0	-18.3, 29.5	-18.3, 29.5	0.0, 0.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	-16.7, 50.0	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Mean Diff (95% CI) [a]			3.0 (-8.0, 14.0)			0.0 (0.0, 0.0)
		P-value [a]			0.553			NE
		Mean Diff (95% CI) [b]			3.0 (-18.2, 24.2)			
		P-value [b]			0.761			
		Effect Size (95% CI) [c]			0.18 (-0.03, 0.39)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	3.3	15.0	11.7	8.3	8.3	0.0
		SD	7.03	26.59	23.64	11.79	11.79	0.00
		95% CI	-1.7, 8.4	-4.0, 34.0	-5.2, 28.6	-97.6, 114.2	-97.6, 114.2	0.0, 0.0
		Median	0.0	0.0	0.0	8.3	8.3	0.0
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Min, Max	0.0, 16.7	0.0, 83.3	-16.7, 66.7	0.0, 16.7	0.0, 16.7	0.0, 0.0
		Mean Diff (95% CI) [a]			11.7 (-5.2, 28.6)			0.0 (0.0, 0.0)
		P-value [a]			0.153			NE
		Mean Diff (95% CI) [b]			11.7 (-27.0, 50.4)			
		P-value [b]			0.517			
		Effect Size (95% CI) [c]			0.70 (0.48, 0.92)			
	C25D1	N	9	9	9	0	0	0
		Mean	3.7	3.7	0.0	NE	NE	NE
		SD	7.35	7.35	8.33	NE	NE	NE
		95% CI	-1.9, 9.4	-1.9, 9.4	-6.4, 6.4	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 16.7	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (-6.4, 6.4)			NE (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	2.1	6.3	4.2	0.0	0.0	0.0
		SD	5.89	17.68	19.42	NE	NE	NE
		95% CI	-2.8, 7.0	-8.5, 21.0	-12.1, 20.4	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 16.7	0.0, 50.0	-16.7, 50.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			4.2 (-12.1, 20.4)			0.0 (NE, NE)
		P-value [a]			0.563			NE
		Mean Diff (95% CI) [b]			4.2 (-44.5, 52.9)			
		P-value [b]			0.845			
		Effect Size (95% CI) [c]			0.25 (0.04, 0.46)			
	C27D1	N	8	8	8	1	1	1
		Mean	2.1	0.0	-2.1	0.0	0.0	0.0
		SD	5.89	0.00	5.89	NE	NE	NE
		95% CI	-2.8, 7.0	0.0, 0.0	-7.0, 2.8	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 16.7	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-2.1 (-7.0, 2.8)			0.0 (NE, NE)
		P-value [a]			0.351			NE
		Mean Diff (95% CI) [b]			-2.1 (-16.9, 12.7)			
		P-value [b]			0.749			
		Effect Size (95% CI) [c]			-0.12 (-0.34, 0.09)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	2.4	0.0	-2.4	0.0	0.0	0.0
		SD	6.30	0.00	6.30	NE	NE	NE
		95% CI	-3.4, 8.2	0.0, 0.0	-8.2, 3.4	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 16.7	0.0, 0.0	-16.7, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-2.4 (-8.2, 3.4)			0.0 (NE, NE)
		P-value [a]			0.356			NE
		Mean Diff (95% CI) [b]			-2.4 (-18.9, 14.1)			
		P-value [b]			0.736			
		Effect Size (95% CI) [c]			-0.14 (-0.36, 0.07)			
	C29D1	N	4	4	4	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
	C31D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
	C33D1	N	3	3	3	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	130	130	130	126	126	126
		Mean	8.7	13.2	4.5	7.5	10.6	3.0
		SD	16.37	19.87	19.55	16.28	20.40	20.37
		95% CI	5.9, 11.6	9.8, 16.7	1.1, 7.9	4.7, 10.4	7.0, 14.2	-0.5, 6.6
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7	0.0, 16.7
		Min, Max	0.0, 83.3	0.0, 100.0	-50.0, 83.3	0.0, 83.3	0.0, 100.0	-66.7, 83.3
		Mean Diff (95% CI) [a]			4.5 (1.1, 7.9)			3.0 (-0.5, 6.6)
		P-value [a]			0.010			0.096
		Mean Diff (95% CI) [b]			1.4 (-3.5, 6.4)			
		P-value [b]			0.563			
		Effect Size (95% CI) [c]			0.09 (-0.13, 0.30)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	6.0	1.2	-4.8	3.7	24.1	20.4
		SD	15.48	4.45	16.57	7.35	33.45	36.11
		95% CI	-3.0, 14.9	-1.4, 3.8	-14.3, 4.8	-1.9, 9.4	-1.6, 49.8	-7.4, 48.1
		Median	0.0	0.0	0.0	0.0	16.7	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 50.0	0.0, 16.7	-50.0, 16.7	0.0, 16.7	0.0, 100.0	-16.7, 100.0
		Mean Diff (95% CI) [a]			-4.8 (-14.3, 4.8)			20.4 (-7.4, 48.1)
		P-value [a]			0.302			0.129
		Mean Diff (95% CI) [b]			-25.1 (-48.1, -2.2)			
		P-value [b]			0.033			
		Effect Size (95% CI) [c]			-1.51 (-1.75, -1.26)			
Pain	Baseline	N	174			165		
		Mean	28.6			30.9		
		SD	27.62			27.00		
		95% CI	24.5, 32.8			26.8, 35.1		
		Median	25.0			33.3		
		Q1, Q3	0.0, 50.0			16.7, 50.0		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	145	145	145
		Mean	27.1	25.8	-1.3	29.4	29.1	-0.3
		SD	27.52	24.70	24.97	26.72	27.27	24.49
		Median	16.7	16.7	0.0	16.7	16.7	0.0
		95% CI	22.7, 31.5	21.8, 29.7	-5.3, 2.7	25.0, 33.8	24.6, 33.6	-4.4, 3.7
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 16.7	0.0, 33.3	16.7, 33.3	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 83.3	0.0, 100.0	0.0, 100.0	-66.7, 83.3
		Mean Diff (95% CI) [a]			-1.3 (-5.3, 2.7)			-0.3 (-4.4, 3.7)
		P-value [a]			0.517			0.866
		Mean Diff (95% CI) [b]			-1.0 (-6.6, 4.7)			
		P-value [b]			0.736			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.18)			
	C3D1	N	124	124	124	102	102	102
		Mean	27.8	22.3	-5.5	27.6	25.5	-2.1
		SD	27.19	22.98	23.73	26.27	25.23	25.01
		Median	16.7	16.7	0.0	16.7	16.7	0.0
		95% CI	23.0, 32.7	18.2, 26.4	-9.7, -1.3	22.5, 32.8	20.5, 30.4	-7.0, 2.8
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 50.0	0.0, 33.3	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 50.0	0.0, 100.0	0.0, 100.0	-83.3, 66.7
		Mean Diff (95% CI) [a]			-5.5 (-9.7, -1.3)			-2.1 (-7.0, 2.8)
		P-value [a]			0.011			0.393
		Mean Diff (95% CI) [b]			-3.4 (-9.8, 3.0)			
		P-value [b]			0.299			
		Effect Size (95% CI) [c]			-0.12 (-0.34, 0.09)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	31.0	22.8	-8.2	29.6	25.5	-4.1
		SD	28.02	24.20	28.56	26.11	27.18	24.52
		Median	33.3	16.7	0.0	33.3	16.7	0.0
		95% CI	25.7, 36.2	18.2, 27.3	-13.5, -2.8	24.3, 35.0	20.0, 31.1	-9.1, 0.9
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 50.0	0.0, 33.3	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 83.3
		Mean Diff (95% CI) [a]			-8.2 (-13.5, -2.8)			-4.1 (-9.1, 0.9)
		P-value [a]			0.003			0.110
		Mean Diff (95% CI) [b]			-4.1 (-11.5, 3.3)			
		P-value [b]			0.275			
		Effect Size (95% CI) [c]			-0.15 (-0.36, 0.06)			
	C5D1	N	98	98	98	80	80	80
		Mean	28.9	20.9	-8.0	30.0	26.5	-3.5
		SD	27.45	21.71	24.43	26.97	27.77	26.48
		Median	16.7	16.7	0.0	33.3	16.7	0.0
		95% CI	23.4, 34.4	16.6, 25.3	-12.9, -3.1	24.0, 36.0	20.3, 32.6	-9.4, 2.4
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 50.0	0.0, 50.0	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-8.0 (-12.9, -3.1)			-3.5 (-9.4, 2.4)
		P-value [a]			0.002			0.235
		Mean Diff (95% CI) [b]			-4.5 (-12.0, 3.1)			
		P-value [b]			0.246			
		Effect Size (95% CI) [c]			-0.16 (-0.38, 0.05)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	69	69	69
		Mean	28.6	20.0	-8.7	30.2	27.8	-2.4
		SD	27.22	22.11	25.59	27.61	28.68	26.39
		Median	16.7	16.7	0.0	16.7	16.7	0.0
		95% CI	23.1, 34.2	15.5, 24.4	-13.9, -3.5	23.6, 36.8	20.9, 34.7	-8.8, 3.9
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 50.0	0.0, 50.0	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-8.7 (-13.9, -3.5)			-2.4 (-8.8, 3.9)
		P-value [a]			0.001			0.450
		Mean Diff (95% CI) [b]			-6.3 (-14.3, 1.8)			
		P-value [b]			0.128			
		Effect Size (95% CI) [c]			-0.23 (-0.44, -0.02)			
	C7D1	N	79	79	79	53	53	53
		Mean	29.3	20.5	-8.9	28.3	20.1	-8.2
		SD	28.14	21.84	23.09	28.23	26.02	24.60
		Median	16.7	16.7	0.0	16.7	16.7	0.0
		95% CI	23.0, 35.6	15.6, 25.4	-14.0, -3.7	20.5, 36.1	13.0, 27.3	-15.0, -1.4
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 50.0	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-83.3, 33.3	0.0, 100.0	0.0, 100.0	-66.7, 50.0
		Mean Diff (95% CI) [a]			-8.9 (-14.0, -3.7)			-8.2 (-15.0, -1.4)
		P-value [a]			0.001			0.019
		Mean Diff (95% CI) [b]			-0.7 (-9.0, 7.6)			
		P-value [b]			0.871			
		Effect Size (95% CI) [c]			-0.03 (-0.24, 0.19)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	29.8	20.4	-9.4	28.7	19.3	-9.3
		SD	27.40	22.21	23.31	28.58	25.28	23.37
		Median	16.7	16.7	0.0	16.7	8.3	0.0
		95% CI	23.6, 36.1	15.3, 25.5	-14.8, -4.1	20.5, 36.8	12.1, 26.5	-16.0, -2.7
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 50.0	0.0, 33.3	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-83.3, 33.3	0.0, 100.0	0.0, 100.0	-66.7, 50.0
		Mean Diff (95% CI) [a]			-9.4 (-14.8, -4.1)			-9.3 (-16.0, -2.7)
		P-value [a]			0.001			0.007
		Mean Diff (95% CI) [b]			-0.1 (-8.5, 8.3)			
		P-value [b]			0.982			
		Effect Size (95% CI) [c]			0.00 (-0.22, 0.21)			
	C9D1	N	60	60	60	42	42	42
		Mean	25.8	21.7	-4.2	30.2	25.0	-5.2
		SD	25.93	24.61	22.89	29.50	28.57	27.67
		Median	16.7	16.7	0.0	16.7	16.7	0.0
		95% CI	19.1, 32.5	15.3, 28.0	-10.1, 1.7	21.0, 39.4	16.1, 33.9	-13.8, 3.5
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 66.7	0.0, 33.3	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 83.3	-66.7, 50.0	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-4.2 (-10.1, 1.7)			-5.2 (-13.8, 3.5)
		P-value [a]			0.164			0.234
		Mean Diff (95% CI) [b]			1.0 (-9.0, 11.0)			
		P-value [b]			0.844			
		Effect Size (95% CI) [c]			0.04 (-0.18, 0.25)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	26.9	23.5	-3.4	36.1	26.7	-9.4
		SD	26.78	24.98	23.43	30.03	26.84	23.03
		Median	16.7	16.7	0.0	33.3	25.0	0.0
		95% CI	19.5, 34.2	16.6, 30.3	-9.8, 3.0	24.9, 47.3	16.6, 36.7	-18.0, -0.8
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	16.7, 66.7	0.0, 50.0	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 66.7	0.0, 100.0	0.0, 100.0	-50.0, 50.0
		Mean Diff (95% CI) [a]			-3.4 (-9.8, 3.0)			-9.4 (-18.0, -0.8)
		P-value [a]			0.292			0.032
		Mean Diff (95% CI) [b]			6.0 (-4.5, 16.6)			
		P-value [b]			0.257			
		Effect Size (95% CI) [c]			0.22 (0.01, 0.43)			
	C11D1	N	46	46	46	23	23	23
		Mean	28.6	23.6	-5.1	25.4	22.5	-2.9
		SD	27.14	26.66	25.79	25.56	19.85	27.82
		Median	16.7	16.7	0.0	16.7	16.7	0.0
		95% CI	20.6, 36.7	15.6, 31.5	-12.7, 2.6	14.3, 36.4	13.9, 31.0	-14.9, 9.1
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 16.7	0.0, 33.3	0.0, 33.3	-33.3, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-50.0, 50.0	0.0, 83.3	0.0, 50.0	-50.0, 50.0
		Mean Diff (95% CI) [a]			-5.1 (-12.7, 2.6)			-2.9 (-14.9, 9.1)
		P-value [a]			0.189			0.622
		Mean Diff (95% CI) [b]			-2.2 (-15.7, 11.3)			
		P-value [b]			0.749			
		Effect Size (95% CI) [c]			-0.08 (-0.29, 0.13)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	28.5	22.4	-6.1	27.2	21.9	-5.3
		SD	25.89	26.77	22.90	23.71	27.25	37.29
		Median	16.7	16.7	0.0	16.7	16.7	0.0
		95% CI	20.3, 36.6	13.9, 30.8	-13.3, 1.1	15.8, 38.6	8.8, 35.1	-23.2, 12.7
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 50.0	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 83.3	-50.0, 50.0	0.0, 66.7	0.0, 83.3	-66.7, 66.7
		Mean Diff (95% CI) [a]			-6.1 (-13.3, 1.1)			-5.3 (-23.2, 12.7)
		P-value [a]			0.096			0.546
		Mean Diff (95% CI) [b]			-0.8 (-16.5, 14.8)			
		P-value [b]			0.915			
		Effect Size (95% CI) [c]			-0.03 (-0.24, 0.18)			
	C13D1	N	33	33	33	15	15	15
		Mean	25.3	18.2	-7.1	28.9	20.0	-8.9
		SD	23.98	22.19	23.95	28.50	25.35	35.56
		Median	16.7	0.0	0.0	16.7	0.0	-16.7
		95% CI	16.7, 33.8	10.3, 26.1	-15.6, 1.4	13.1, 44.7	6.0, 34.0	-28.6, 10.8
		Q1, Q3	0.0, 50.0	0.0, 33.3	-33.3, 0.0	0.0, 50.0	0.0, 33.3	-33.3, 16.7
		Min, Max	0.0, 66.7	0.0, 66.7	-50.0, 33.3	0.0, 83.3	0.0, 66.7	-50.0, 66.7
		Mean Diff (95% CI) [a]			-7.1 (-15.6, 1.4)			-8.9 (-28.6, 10.8)
		P-value [a]			0.100			0.349
		Mean Diff (95% CI) [b]			1.8 (-15.7, 19.4)			
		P-value [b]			0.836			
		Effect Size (95% CI) [c]			0.07 (-0.15, 0.28)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	25.8	20.7	-5.1	30.6	23.6	-6.9
		SD	24.33	24.66	23.75	30.01	33.68	31.35
		Median	16.7	16.7	0.0	25.0	0.0	-16.7
		95% CI	17.1, 34.4	12.0, 29.5	-13.5, 3.4	11.5, 49.6	2.2, 45.0	-26.9, 13.0
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 16.7	0.0, 58.3	0.0, 41.7	-33.3, 16.7
		Min, Max	0.0, 66.7	0.0, 83.3	-50.0, 33.3	0.0, 83.3	0.0, 100.0	-50.0, 50.0
		Mean Diff (95% CI) [a]			-5.1 (-13.5, 3.4)			-6.9 (-26.9, 13.0)
		P-value [a]			0.231			0.459
		Mean Diff (95% CI) [b]			1.9 (-15.7, 19.5)			
		P-value [b]			0.829			
		Effect Size (95% CI) [c]			0.07 (-0.14, 0.28)			
	C15D1	N	28	28	28	13	13	13
		Mean	26.8	18.5	-8.3	32.1	29.5	-2.6
		SD	24.99	21.91	23.79	29.24	26.49	27.93
		Median	16.7	8.3	0.0	33.3	33.3	0.0
		95% CI	17.1, 36.5	10.0, 26.9	-17.6, 0.9	14.4, 49.7	13.5, 45.5	-19.4, 14.3
		Q1, Q3	0.0, 50.0	0.0, 33.3	-25.0, 8.3	0.0, 50.0	0.0, 33.3	-16.7, 16.7
		Min, Max	0.0, 66.7	0.0, 66.7	-50.0, 33.3	0.0, 83.3	0.0, 83.3	-50.0, 33.3
		Mean Diff (95% CI) [a]			-8.3 (-17.6, 0.9)			-2.6 (-19.4, 14.3)
		P-value [a]			0.075			0.746
		Mean Diff (95% CI) [b]			-5.8 (-22.8, 11.3)			
		P-value [b]			0.498			
		Effect Size (95% CI) [c]			-0.21 (-0.42, 0.00)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	27.4	20.2	-7.1	35.0	28.3	-6.7
		SD	24.52	22.39	21.96	31.87	28.38	25.09
		Median	16.7	16.7	0.0	33.3	25.0	-8.3
		95% CI	17.9, 36.9	11.6, 28.9	-15.7, 1.4	12.2, 57.8	8.0, 48.6	-24.6, 11.3
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	0.0, 66.7	0.0, 33.3	-16.7, 16.7
		Min, Max	0.0, 66.7	0.0, 66.7	-50.0, 33.3	0.0, 83.3	0.0, 83.3	-50.0, 33.3
		Mean Diff (95% CI) [a]			-7.1 (-15.7, 1.4)			-6.7 (-24.6, 11.3)
		P-value [a]			0.097			0.423
		Mean Diff (95% CI) [b]			-0.5 (-17.5, 16.5)			
		P-value [b]			0.955			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.20)			
	C17D1	N	26	26	26	7	7	7
		Mean	26.9	20.5	-6.4	42.9	26.2	-16.7
		SD	24.98	25.52	23.61	31.71	30.21	21.52
		Median	16.7	16.7	0.0	50.0	16.7	-16.7
		95% CI	16.8, 37.0	10.2, 30.8	-15.9, 3.1	13.5, 72.2	-1.7, 54.1	-36.6, 3.2
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	16.7, 66.7	0.0, 66.7	-33.3, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-50.0, 50.0	0.0, 83.3	0.0, 66.7	-50.0, 16.7
		Mean Diff (95% CI) [a]			-6.4 (-15.9, 3.1)			-16.7 (-36.6, 3.2)
		P-value [a]			0.178			0.086
		Mean Diff (95% CI) [b]			10.3 (-9.9, 30.4)			
		P-value [b]			0.308			
		Effect Size (95% CI) [c]			0.37 (0.16, 0.59)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	28.8	21.2	-7.6	33.3	16.7	-16.7
		SD	25.29	28.26	25.58	33.33	21.52	28.87
		Median	16.7	0.0	0.0	16.7	0.0	-16.7
		95% CI	17.6, 40.0	8.7, 33.7	-18.9, 3.8	2.5, 64.2	-3.2, 36.6	-43.4, 10.0
		Q1, Q3	0.0, 50.0	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 33.3	-50.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-50.0, 50.0	0.0, 83.3	0.0, 50.0	-50.0, 33.3
		Mean Diff (95% CI) [a]			-7.6 (-18.9, 3.8)			-16.7 (-43.4, 10.0)
		P-value [a]			0.179			0.177
		Mean Diff (95% CI) [b]			9.1 (-14.4, 32.5)			
		P-value [b]			0.433			
		Effect Size (95% CI) [c]			0.33 (0.12, 0.55)			
	C19D1	N	20	20	20	6	6	6
		Mean	29.2	25.0	-4.2	27.8	30.6	2.8
		SD	25.29	27.84	26.42	32.77	19.48	22.15
		Median	16.7	16.7	0.0	16.7	25.0	16.7
		95% CI	17.3, 41.0	12.0, 38.0	-16.5, 8.2	-6.6, 62.2	10.1, 51.0	-20.5, 26.0
		Q1, Q3	8.3, 50.0	0.0, 33.3	-25.0, 16.7	0.0, 50.0	16.7, 33.3	-16.7, 16.7
		Min, Max	0.0, 66.7	0.0, 83.3	-50.0, 50.0	0.0, 83.3	16.7, 66.7	-33.3, 16.7
		Mean Diff (95% CI) [a]			-4.2 (-16.5, 8.2)			2.8 (-20.5, 26.0)
		P-value [a]			0.489			0.771
		Mean Diff (95% CI) [b]			-6.9 (-31.5, 17.6)			
		P-value [b]			0.565			
		Effect Size (95% CI) [c]			-0.25 (-0.47, -0.04)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	23.3	27.5	4.2	41.7	25.0	-16.7
		SD	24.42	26.64	20.86	31.91	28.87	13.61
		Median	16.7	25.0	0.0	33.3	16.7	-16.7
		95% CI	11.9, 34.8	15.0, 40.0	-5.6, 13.9	-9.1, 92.4	-20.9, 70.9	-38.3, 5.0
		Q1, Q3	0.0, 41.7	0.0, 41.7	0.0, 16.7	16.7, 66.7	8.3, 41.7	-25.0, -8.3
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 50.0	16.7, 83.3	0.0, 66.7	-33.3, 0.0
		Mean Diff (95% CI) [a]			4.2 (-5.6, 13.9)			-16.7 (-38.3, 5.0)
		P-value [a]			0.383			0.092
		Mean Diff (95% CI) [b]			20.8 (-1.9, 43.6)			
		P-value [b]			0.071			
		Effect Size (95% CI) [c]			0.76 (0.54, 0.98)			
	C21D1	N	18	18	18	4	4	4
		Mean	25.9	19.4	-6.5	41.7	25.0	-16.7
		SD	24.40	18.30	18.20	31.91	28.87	13.61
		Median	16.7	16.7	0.0	33.3	16.7	-16.7
		95% CI	13.8, 38.1	10.3, 28.5	-15.5, 2.6	-9.1, 92.4	-20.9, 70.9	-38.3, 5.0
		Q1, Q3	0.0, 50.0	0.0, 33.3	-16.7, 0.0	16.7, 66.7	8.3, 41.7	-25.0, -8.3
		Min, Max	0.0, 66.7	0.0, 66.7	-50.0, 16.7	16.7, 83.3	0.0, 66.7	-33.3, 0.0
		Mean Diff (95% CI) [a]			-6.5 (-15.5, 2.6)			-16.7 (-38.3, 5.0)
		P-value [a]			0.149			0.092
		Mean Diff (95% CI) [b]			10.2 (-10.1, 30.5)			
		P-value [b]			0.307			
		Effect Size (95% CI) [c]			0.37 (0.16, 0.59)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	21.1	24.4	3.3	50.0	22.2	-27.8
		SD	23.12	26.63	26.13	33.33	19.25	19.25
		Median	16.7	16.7	0.0	50.0	33.3	-16.7
		95% CI	8.3, 33.9	9.7, 39.2	-11.1, 17.8	-32.8, 132.8	-25.6, 70.0	-75.6, 20.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 16.7	16.7, 83.3	0.0, 33.3	-50.0, -16.7
		Min, Max	0.0, 66.7	0.0, 83.3	-50.0, 66.7	16.7, 83.3	0.0, 33.3	-50.0, -16.7
		Mean Diff (95% CI) [a]			3.3 (-11.1, 17.8)			-27.8 (-75.6, 20.0)
		P-value [a]			0.629			0.130
		Mean Diff (95% CI) [b]			31.1 (-2.9, 65.1)			
		P-value [b]			0.070			
		Effect Size (95% CI) [c]			1.14 (0.91, 1.37)			
	C23D1	N	11	11	11	3	3	3
		Mean	22.7	19.7	-3.0	50.0	27.8	-22.2
		SD	23.89	22.13	19.46	33.33	34.69	9.62
		Median	16.7	16.7	0.0	50.0	16.7	-16.7
		95% CI	6.7, 38.8	4.8, 34.6	-16.1, 10.0	-32.8, 132.8	-58.4, 114.0	-46.1, 1.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	-16.7, 16.7	16.7, 83.3	0.0, 66.7	-33.3, -16.7
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 16.7	16.7, 83.3	0.0, 66.7	-33.3, -16.7
		Mean Diff (95% CI) [a]			-3.0 (-16.1, 10.0)			-22.2 (-46.1, 1.7)
		P-value [a]			0.617			0.057
		Mean Diff (95% CI) [b]			19.2 (-6.6, 45.0)			
		P-value [b]			0.131			
		Effect Size (95% CI) [c]			0.70 (0.48, 0.92)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	18.3	25.0	6.7	50.0	33.3	-16.7
		SD	19.95	29.66	25.09	47.14	47.14	0.00
		Median	16.7	16.7	8.3	50.0	33.3	-16.7
		95% CI	4.1, 32.6	3.8, 46.2	-11.3, 24.6	-373.5, 473.5	-390.2, 456.9	-16.7, -16.7
		Q1, Q3	0.0, 16.7	0.0, 50.0	-16.7, 16.7	16.7, 83.3	0.0, 66.7	-16.7, -16.7
		Min, Max	0.0, 66.7	0.0, 83.3	-33.3, 50.0	16.7, 83.3	0.0, 66.7	-16.7, -16.7
		Mean Diff (95% CI) [a]			6.7 (-11.3, 24.6)			-16.7 (-16.7, -16.7)
		P-value [a]			0.423			<.001
		Mean Diff (95% CI) [b]			23.3 (-17.8, 64.4)			
		P-value [b]			0.234			
		Effect Size (95% CI) [c]			0.85 (0.63, 1.07)			
	C25D1	N	9	9	9	0	0	0
		Mean	20.4	24.1	3.7	NE	NE	NE
		SD	20.03	32.39	24.69	NE	NE	NE
		Median	16.7	0.0	0.0	NE	NE	NE
		95% CI	5.0, 35.8	-0.8, 49.0	-15.3, 22.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	16.7, 16.7	0.0, 33.3	-16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 66.7	0.0, 83.3	-33.3, 50.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			3.7 (-15.3, 22.7)			NE (NE, NE)
		P-value [a]			0.665			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	14.6	18.8	4.2	16.7	16.7	0.0
		SD	10.68	27.37	27.82	NE	NE	NE
		Median	16.7	0.0	0.0	16.7	16.7	0.0
		95% CI	5.7, 23.5	-4.1, 41.6	-19.1, 27.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	8.3, 16.7	0.0, 41.7	-16.7, 25.0	16.7, 16.7	16.7, 16.7	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	-33.3, 50.0	16.7, 16.7	16.7, 16.7	0.0, 0.0
		Mean Diff (95% CI) [a]			4.2 (-19.1, 27.4)			0.0 (NE, NE)
		P-value [a]			0.685			NE
		Mean Diff (95% CI) [b]			4.2 (-65.6, 73.9)			
		P-value [b]			0.892			
		Effect Size (95% CI) [c]			0.15 (-0.06, 0.36)			
	C27D1	N	8	8	8	1	1	1
		Mean	14.6	8.3	-6.3	16.7	0.0	-16.7
		SD	10.68	15.43	17.68	NE	NE	NE
		Median	16.7	0.0	-8.3	16.7	0.0	-16.7
		95% CI	5.7, 23.5	-4.6, 21.2	-21.0, 8.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	8.3, 16.7	0.0, 16.7	-16.7, 8.3	16.7, 16.7	0.0, 0.0	-16.7, -16.7
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 16.7	16.7, 16.7	0.0, 0.0	-16.7, -16.7
		Mean Diff (95% CI) [a]			-6.3 (-21.0, 8.5)			-16.7 (NE, NE)
		P-value [a]			0.351			NE
		Mean Diff (95% CI) [b]			10.4 (-33.9, 54.8)			
		P-value [b]			0.596			
		Effect Size (95% CI) [c]			0.38 (0.17, 0.59)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	14.3	21.4	7.1	16.7	0.0	-16.7
		SD	11.50	18.54	21.21	NE	NE	NE
		Median	16.7	16.7	16.7	16.7	0.0	-16.7
		95% CI	3.6, 24.9	4.3, 38.6	-12.5, 26.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 16.7	16.7, 16.7	0.0, 0.0	-16.7, -16.7
		Min, Max	0.0, 33.3	0.0, 50.0	-33.3, 33.3	16.7, 16.7	0.0, 0.0	-16.7, -16.7
		Mean Diff (95% CI) [a]			7.1 (-12.5, 26.8)			-16.7 (NE, NE)
		P-value [a]			0.407			NE
		Mean Diff (95% CI) [b]			23.8 (-31.7, 79.3)			
		P-value [b]			0.334			
		Effect Size (95% CI) [c]			0.87 (0.65, 1.09)			
	C29D1	N	4	4	4	1	1	1
		Mean	12.5	16.7	4.2	16.7	100.0	83.3
		SD	8.33	19.25	15.96	NE	NE	NE
		Median	16.7	16.7	8.3	16.7	100.0	83.3
		95% CI	-0.8, 25.8	-14.0, 47.3	-21.2, 29.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	8.3, 16.7	0.0, 33.3	-8.3, 16.7	16.7, 16.7	100.0, 100.0	83.3, 83.3
		Min, Max	0.0, 16.7	0.0, 33.3	-16.7, 16.7	16.7, 16.7	100.0, 100.0	83.3, 83.3
		Mean Diff (95% CI) [a]			4.2 (-21.2, 29.6)			83.3 (NE, NE)
		P-value [a]			0.638			NE
		Mean Diff (95% CI) [b]			-79.2 (-135.9, -22.4)			
		P-value [b]			0.021			
		Effect Size (95% CI) [c]			-2.89 (-3.20, -2.59)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	8.3	8.3	0.0	16.7	100.0	83.3
		SD	9.62	16.67	13.61	NE	NE	NE
		Median	8.3	0.0	0.0	16.7	100.0	83.3
		95% CI	-7.0, 23.6	-18.2, 34.9	-21.7, 21.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 16.7	-8.3, 8.3	16.7, 16.7	100.0, 100.0	83.3, 83.3
		Min, Max	0.0, 16.7	0.0, 33.3	-16.7, 16.7	16.7, 16.7	100.0, 100.0	83.3, 83.3
		Mean Diff (95% CI) [a]			0.0 (-21.7, 21.7)			83.3 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			-83.3 (-131.8, -34.9)			
		P-value [b]			0.012			
		Effect Size (95% CI) [c]			-3.04 (-3.36, -2.73)			
	C31D1	N	2	2	2	1	1	1
		Mean	8.3	8.3	0.0	16.7	33.3	16.7
		SD	11.79	11.79	0.00	NE	NE	NE
		Median	8.3	8.3	0.0	16.7	33.3	16.7
		95% CI	-97.6, 114.2	-97.6, 114.2	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	16.7, 16.7	33.3, 33.3	16.7, 16.7
		Min, Max	0.0, 16.7	0.0, 16.7	0.0, 0.0	16.7, 16.7	33.3, 33.3	16.7, 16.7
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			16.7 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-16.7 (-16.7, -16.7)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-0.61 (-0.83, -0.39)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	8.3	0.0	-8.3	16.7	33.3	16.7
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	8.3	0.0	-8.3	16.7	33.3	16.7
		95% CI	-97.6, 114.2	0.0, 0.0	-114.2, 97.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 0.0	-16.7, 0.0	16.7, 16.7	33.3, 33.3	16.7, 16.7
		Min, Max	0.0, 16.7	0.0, 0.0	-16.7, 0.0	16.7, 16.7	33.3, 33.3	16.7, 16.7
		Mean Diff (95% CI) [a]			-8.3 (-114.2, 97.6)			16.7 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			-25.0 (-208.4, 158.4)			
		P-value [b]			0.333			
		Effect Size (95% CI) [c]			-0.91 (-1.14, -0.69)			
	C33D1	N	3	3	3	1	1	1
		Mean	5.6	22.2	16.7	16.7	33.3	16.7
		SD	9.62	19.25	16.67	NE	NE	NE
		Median	0.0	33.3	16.7	16.7	33.3	16.7
		95% CI	-18.3, 29.5	-25.6, 70.0	-24.7, 58.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 33.3	16.7, 16.7	33.3, 33.3	16.7, 16.7
		Min, Max	0.0, 16.7	0.0, 33.3	0.0, 33.3	16.7, 16.7	33.3, 33.3	16.7, 16.7
		Mean Diff (95% CI) [a]			16.7 (-24.7, 58.1)			16.7 (NE, NE)
		P-value [a]			0.225			NE
		Mean Diff (95% CI) [b]			0.0 (-82.8, 82.8)			
		P-value [b]			1.000			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	5.6	16.7	11.1	NE	NE	NE
		SD	9.62	16.67	19.25	NE	NE	NE
		Median	0.0	16.7	0.0	NE	NE	NE
		95% CI	-18.3, 29.5	-24.7, 58.1	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	8.3	16.7	8.3	NE	NE	NE
		SD	11.79	23.57	35.36	NE	NE	NE
		Median	8.3	16.7	8.3	NE	NE	NE
		95% CI	-97.6, 114.2	-195.1, 228.4	-309.3, 326.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	-16.7, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 33.3	-16.7, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-309.3, 326.0)			NE (NE, NE)
		P-value [a]			0.795			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	5.6	11.1	5.6	NE	NE	NE
		SD	9.62	19.25	25.46	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	-18.3, 29.5	-36.7, 58.9	-57.7, 68.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	-16.7, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 33.3	-16.7, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			5.6 (-57.7, 68.8)			NE (NE, NE)
		P-value [a]			0.742			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	5.6	11.1	5.6	NE	NE	NE
		SD	9.62	19.25	25.46	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	-18.3, 29.5	-36.7, 58.9	-57.7, 68.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	-16.7, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 33.3	-16.7, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			5.6 (-57.7, 68.8)			NE (NE, NE)
		P-value [a]			0.742			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	8.3	16.7	8.3	NE	NE	NE
		SD	11.79	23.57	11.79	NE	NE	NE
		Median	8.3	16.7	8.3	NE	NE	NE
		95% CI	-97.6, 114.2	-195.1, 228.4	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 33.3	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	8.3	0.0	-8.3	NE	NE	NE
		SD	11.79	0.00	11.79	NE	NE	NE
		Median	8.3	0.0	-8.3	NE	NE	NE
		95% CI	-97.6, 114.2	0.0, 0.0	-114.2, 97.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 0.0	-16.7, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 0.0	-16.7, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-8.3 (-114.2, 97.6)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	8.3	8.3	0.0	NE	NE	NE
		SD	11.79	11.79	0.00	NE	NE	NE
		Median	8.3	8.3	0.0	NE	NE	NE
		95% CI	-97.6, 114.2	-97.6, 114.2	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 16.7	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	8.3	16.7	8.3	NE	NE	NE
		SD	11.79	23.57	11.79	NE	NE	NE
		Median	8.3	16.7	8.3	NE	NE	NE
		95% CI	-97.6, 114.2	-195.1, 228.4	-97.6, 114.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 16.7	0.0, 33.3	0.0, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.3 (-97.6, 114.2)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	16.7	33.3	16.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	16.7	33.3	16.7	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	16.7, 16.7	33.3, 33.3	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Min, Max	16.7, 16.7	33.3, 33.3	16.7, 16.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	16.7	16.7	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	16.7	16.7	0.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	16.7, 16.7	16.7, 16.7	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	16.7, 16.7	16.7, 16.7	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	126	126	126
		Mean	28.8	29.3	0.5	32.4	32.9	0.5
		SD	27.12	31.22	27.03	27.59	30.15	27.32
		Median	33.3	16.7	0.0	33.3	33.3	0.0
		95% CI	24.1, 33.4	23.9, 34.7	-4.2, 5.2	27.5, 37.3	27.6, 38.3	-4.3, 5.3
		Q1, Q3	0.0, 50.0	0.0, 50.0	-16.7, 16.7	16.7, 50.0	0.0, 50.0	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 83.3	0.0, 100.0	0.0, 100.0	-66.7, 83.3
		Mean Diff (95% CI) [a]			0.5 (-4.2, 5.2)			0.5 (-4.3, 5.3)
		P-value [a]			0.830			0.828
		Mean Diff (95% CI) [b]			0.0 (-6.7, 6.7)			
		P-value [b]			0.995			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	19.0	21.4	2.4	29.6	44.4	14.8
		SD	26.03	29.55	21.54	20.03	40.82	33.79
		Median	0.0	8.3	0.0	33.3	33.3	0.0
		95% CI	4.0, 34.1	4.4, 38.5	-10.1, 14.8	14.2, 45.0	13.1, 75.8	-11.2, 40.8
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 16.7	16.7, 33.3	16.7, 83.3	-16.7, 33.3
		Min, Max	0.0, 66.7	0.0, 100.0	-50.0, 50.0	0.0, 66.7	0.0, 100.0	-16.7, 83.3
		Mean Diff (95% CI) [a]			2.4 (-10.1, 14.8)			14.8 (-11.2, 40.8)
		P-value [a]			0.686			0.225
		Mean Diff (95% CI) [b]			-12.4 (-36.3, 11.4)			
		P-value [b]			0.291			
		Effect Size (95% CI) [c]			-0.45 (-0.67, -0.24)			
Dyspnea	Baseline	N	173			165		
		Mean	18.5			21.8		
		SD	23.94			27.71		
		Median	0.0			0.0		
		95% CI	14.9, 22.1			17.6, 26.1		
		Q1, Q3	0.0, 33.3			0.0, 33.3		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	151	152	151	144	144	144
		Mean	16.8	21.3	4.6	21.5	26.9	5.3
		SD	23.05	26.73	21.44	27.73	30.86	22.18
		95% CI	13.1, 20.5	17.0, 25.6	1.2, 8.1	17.0, 26.1	21.8, 31.9	1.7, 9.0
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			4.6 (1.2, 8.1)			5.3 (1.7, 9.0)
		P-value [a]			0.009			0.005
		Mean Diff (95% CI) [b]			-0.7 (-5.7, 4.3)			
		P-value [b]			0.787			
		Effect Size (95% CI) [c]			-0.03 (-0.24, 0.19)			
	C3D1	N	121	122	121	102	102	102
		Mean	16.0	16.7	0.8	21.2	25.2	3.9
		SD	21.13	23.96	22.55	26.86	28.31	25.82
		95% CI	12.2, 19.8	12.4, 21.0	-3.2, 4.9	16.0, 26.5	19.6, 30.7	-1.1, 9.0
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			0.8 (-3.2, 4.9)			3.9 (-1.1, 9.0)
		P-value [a]			0.688			0.128
		Mean Diff (95% CI) [b]			-3.1 (-9.5, 3.3)			
		P-value [b]			0.340			
		Effect Size (95% CI) [c]			-0.12 (-0.33, 0.09)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	16.7	17.3	0.6	20.9	27.0	6.0
		SD	21.92	24.50	23.24	26.32	28.62	28.06
		95% CI	12.6, 20.8	12.7, 21.8	-3.8, 4.9	15.5, 26.3	21.1, 32.8	0.3, 11.8
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 66.7	0.0, 100.0	0.0, 100.0	-33.3, 100.0
		Mean Diff (95% CI) [a]			0.6 (-3.8, 4.9)			6.0 (0.3, 11.8)
		P-value [a]			0.787			0.040
		Mean Diff (95% CI) [b]			-5.4 (-12.5, 1.6)			
		P-value [b]			0.130			
		Effect Size (95% CI) [c]			-0.21 (-0.42, 0.00)			
	C5D1	N	96	97	96	80	80	80
		Mean	17.0	17.2	0.3	18.3	23.3	5.0
		SD	21.63	22.11	23.94	25.38	27.76	22.56
		95% CI	12.6, 21.4	12.7, 21.6	-4.5, 5.2	12.7, 24.0	17.2, 29.5	0.0, 10.0
		Median	0.0	0.0	0.0	0.0	16.7	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-33.3, 66.7
		Mean Diff (95% CI) [a]			0.3 (-4.5, 5.2)			5.0 (0.0, 10.0)
		P-value [a]			0.887			0.051
		Mean Diff (95% CI) [b]			-4.7 (-11.6, 2.3)			
		P-value [b]			0.189			
		Effect Size (95% CI) [c]			-0.18 (-0.39, 0.03)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	95	96	95	69	69	69
		Mean	15.4	13.9	-1.4	20.3	21.7	1.4
		SD	21.09	20.33	20.58	26.33	26.09	23.18
		95% CI	11.1, 19.7	9.8, 18.0	-5.6, 2.8	14.0, 26.6	15.5, 28.0	-4.1, 7.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-1.4 (-5.6, 2.8)			1.4 (-4.1, 7.0)
		P-value [a]			0.508			0.605
		Mean Diff (95% CI) [b]			-2.9 (-9.6, 3.9)			
		P-value [b]			0.407			
		Effect Size (95% CI) [c]			-0.11 (-0.32, 0.10)			
	C7D1	N	78	78	78	53	53	53
		Mean	15.8	15.4	-0.4	19.5	20.1	0.6
		SD	21.97	23.23	21.15	24.84	27.22	23.10
		95% CI	10.9, 20.8	10.1, 20.6	-5.2, 4.3	12.7, 26.3	12.6, 27.6	-5.7, 7.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 66.7	0.0, 66.7	0.0, 100.0	-33.3, 100.0
		Mean Diff (95% CI) [a]			-0.4 (-5.2, 4.3)			0.6 (-5.7, 7.0)
		P-value [a]			0.859			0.844
		Mean Diff (95% CI) [b]			-1.1 (-8.8, 6.7)			
		P-value [b]			0.787			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.17)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	15.8	14.5	-1.3	18.7	20.0	1.3
		SD	22.09	23.31	20.69	24.43	24.28	20.16
		95% CI	10.7, 20.8	9.1, 19.8	-6.0, 3.4	11.7, 25.6	13.1, 26.9	-4.4, 7.1
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 33.3	0.0, 66.7	0.0, 66.7	-33.3, 66.7
		Mean Diff (95% CI) [a]			-1.3 (-6.0, 3.4)			1.3 (-4.4, 7.1)
		P-value [a]			0.581			0.642
		Mean Diff (95% CI) [b]			-2.6 (-10.0, 4.7)			
		P-value [b]			0.479			
		Effect Size (95% CI) [c]			-0.10 (-0.32, 0.11)			
	C9D1	N	60	60	60	42	42	42
		Mean	14.4	13.9	-0.6	16.7	15.9	-0.8
		SD	21.58	23.20	21.69	24.69	24.68	22.68
		95% CI	8.9, 20.0	7.9, 19.9	-6.2, 5.0	9.0, 24.4	8.2, 23.6	-7.9, 6.3
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 33.3	0.0, 66.7	0.0, 66.7	-66.7, 66.7
		Mean Diff (95% CI) [a]			-0.6 (-6.2, 5.0)			-0.8 (-7.9, 6.3)
		P-value [a]			0.843			0.822
		Mean Diff (95% CI) [b]			0.2 (-8.6, 9.1)			
		P-value [b]			0.957			
		Effect Size (95% CI) [c]			0.01 (-0.20, 0.22)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	13.6	13.0	-0.6	15.6	20.0	4.4
		SD	19.98	18.79	21.95	22.71	24.13	22.71
		95% CI	8.1, 19.0	7.8, 18.1	-6.6, 5.4	7.1, 24.0	11.0, 29.0	-4.0, 12.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	0.0, 66.7	0.0, 66.7	-33.3, 66.7
		Mean Diff (95% CI) [a]			-0.6 (-6.6, 5.4)			4.4 (-4.0, 12.9)
		P-value [a]			0.837			0.293
		Mean Diff (95% CI) [b]			-5.1 (-15.1, 5.0)			
		P-value [b]			0.320			
		Effect Size (95% CI) [c]			-0.20 (-0.41, 0.02)			
	C11D1	N	45	45	45	23	23	23
		Mean	16.3	14.1	-2.2	13.0	20.3	7.2
		SD	22.04	21.89	26.01	19.43	21.88	24.53
		95% CI	9.7, 22.9	7.5, 20.7	-10.0, 5.6	4.6, 21.4	10.8, 29.8	-3.4, 17.9
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 66.7	0.0, 66.7	0.0, 66.7	-33.3, 66.7
		Mean Diff (95% CI) [a]			-2.2 (-10.0, 5.6)			7.2 (-3.4, 17.9)
		P-value [a]			0.570			0.171
		Mean Diff (95% CI) [b]			-9.5 (-22.5, 3.6)			
		P-value [b]			0.153			
		Effect Size (95% CI) [c]			-0.37 (-0.58, -0.15)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	13.8	16.3	2.4	12.3	17.5	5.3
		SD	21.05	22.51	22.84	19.91	17.10	20.07
		95% CI	7.2, 20.5	9.2, 23.4	-4.8, 9.6	2.7, 21.9	9.3, 25.8	-4.4, 14.9
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 66.7	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			2.4 (-4.8, 9.6)			5.3 (-4.4, 14.9)
		P-value [a]			0.498			0.268
		Mean Diff (95% CI) [b]			-2.8 (-15.1, 9.4)			
		P-value [b]			0.646			
		Effect Size (95% CI) [c]			-0.11 (-0.32, 0.10)			
	C13D1	N	32	32	32	15	15	15
		Mean	16.7	16.7	0.0	17.8	20.0	2.2
		SD	22.40	22.40	23.95	24.77	16.90	23.46
		95% CI	8.6, 24.7	8.6, 24.7	-8.6, 8.6	4.1, 31.5	10.6, 29.4	-10.8, 15.2
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (-8.6, 8.6)			2.2 (-10.8, 15.2)
		P-value [a]			1.000			0.719
		Mean Diff (95% CI) [b]			-2.2 (-17.2, 12.8)			
		P-value [b]			0.767			
		Effect Size (95% CI) [c]			-0.09 (-0.30, 0.13)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	16.2	19.2	3.0	11.1	16.7	5.6
		SD	22.24	22.10	22.61	21.71	22.47	12.97
		95% CI	8.3, 24.0	11.4, 27.0	-5.0, 11.0	-2.7, 24.9	2.4, 30.9	-2.7, 13.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 16.7	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	0.0, 66.7	0.0, 66.7	0.0, 33.3
		Mean Diff (95% CI) [a]			3.0 (-5.0, 11.0)			5.6 (-2.7, 13.8)
		P-value [a]			0.447			0.166
		Mean Diff (95% CI) [b]			-2.5 (-16.5, 11.5)			
		P-value [b]			0.718			
		Effect Size (95% CI) [c]			-0.10 (-0.31, 0.12)			
	C15D1	N	28	28	28	13	13	13
		Mean	17.9	19.0	1.2	15.4	33.3	17.9
		SD	23.10	26.34	27.94	25.88	30.43	35.00
		95% CI	8.9, 26.8	8.8, 29.3	-9.6, 12.0	-0.3, 31.0	14.9, 51.7	-3.2, 39.1
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 66.7	0.0, 66.7	0.0, 100.0	-33.3, 100.0
		Mean Diff (95% CI) [a]			1.2 (-9.6, 12.0)			17.9 (-3.2, 39.1)
		P-value [a]			0.823			0.089
		Mean Diff (95% CI) [b]			-16.8 (-37.3, 3.8)			
		P-value [b]			0.107			
		Effect Size (95% CI) [c]			-0.65 (-0.87, -0.43)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	16.7	16.7	0.0	20.0	26.7	6.7
		SD	23.13	21.28	22.22	28.11	21.08	21.08
		95% CI	7.7, 25.6	8.4, 24.9	-8.6, 8.6	-0.1, 40.1	11.6, 41.7	-8.4, 21.7
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	0.0, 66.7	0.0, 66.7	-33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (-8.6, 8.6)			6.7 (-8.4, 21.7)
		P-value [a]			1.000			0.343
		Mean Diff (95% CI) [b]			-6.7 (-23.1, 9.7)			
		P-value [b]			0.415			
		Effect Size (95% CI) [c]			-0.26 (-0.47, -0.04)			
	C17D1	N	26	26	26	7	7	7
		Mean	17.9	15.4	-2.6	19.0	23.8	4.8
		SD	23.53	21.56	22.95	26.23	25.20	12.60
		95% CI	8.4, 27.5	6.7, 24.1	-11.8, 6.7	-5.2, 43.3	0.5, 47.1	-6.9, 16.4
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	0.0, 66.7	0.0, 66.7	0.0, 33.3
		Mean Diff (95% CI) [a]			-2.6 (-11.8, 6.7)			4.8 (-6.9, 16.4)
		P-value [a]			0.574			0.356
		Mean Diff (95% CI) [b]			-7.3 (-25.9, 11.2)			
		P-value [b]			0.426			
		Effect Size (95% CI) [c]			-0.28 (-0.50, -0.07)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	19.7	21.2	1.5	14.3	19.0	4.8
		SD	24.47	21.93	24.07	26.23	17.82	23.00
		95% CI	8.8, 30.5	11.5, 30.9	-9.2, 12.2	-10.0, 38.5	2.6, 35.5	-16.5, 26.0
		Median	0.0	33.3	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			1.5 (-9.2, 12.2)			4.8 (-16.5, 26.0)
		P-value [a]			0.771			0.604
		Mean Diff (95% CI) [b]			-3.2 (-24.5, 18.0)			
		P-value [b]			0.756			
		Effect Size (95% CI) [c]			-0.13 (-0.34, 0.09)			
	C19D1	N	20	20	20	6	6	6
		Mean	15.0	18.3	3.3	16.7	22.2	5.6
		SD	20.16	25.31	26.27	27.89	17.21	25.09
		95% CI	5.6, 24.4	6.5, 30.2	-9.0, 15.6	-12.6, 45.9	4.2, 40.3	-20.8, 31.9
		Median	0.0	0.0	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 66.7	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			3.3 (-9.0, 15.6)			5.6 (-20.8, 31.9)
		P-value [a]			0.577			0.611
		Mean Diff (95% CI) [b]			-2.2 (-27.2, 22.8)			
		P-value [b]			0.856			
		Effect Size (95% CI) [c]			-0.09 (-0.30, 0.13)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	11.7	18.3	6.7	25.0	16.7	-8.3
		SD	19.57	17.01	23.20	31.91	19.25	16.67
		95% CI	2.5, 20.8	10.4, 26.3	-4.2, 17.5	-25.8, 75.8	-14.0, 47.3	-34.9, 18.2
		Median	0.0	33.3	0.0	16.7	16.7	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 50.0	0.0, 33.3	-16.7, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			6.7 (-4.2, 17.5)			-8.3 (-34.9, 18.2)
		P-value [a]			0.214			0.391
		Mean Diff (95% CI) [b]			15.0 (-10.5, 40.5)			
		P-value [b]			0.235			
		Effect Size (95% CI) [c]			0.58 (0.36, 0.80)			
	C21D1	N	18	18	18	4	4	4
		Mean	13.0	18.5	5.6	25.0	16.7	-8.3
		SD	20.26	17.04	20.61	31.91	19.25	16.67
		95% CI	2.9, 23.0	10.0, 27.0	-4.7, 15.8	-25.8, 75.8	-14.0, 47.3	-34.9, 18.2
		Median	0.0	33.3	0.0	16.7	16.7	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 50.0	0.0, 33.3	-16.7, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			5.6 (-4.7, 15.8)			-8.3 (-34.9, 18.2)
		P-value [a]			0.269			0.391
		Mean Diff (95% CI) [b]			13.9 (-9.3, 37.0)			
		P-value [b]			0.225			
		Effect Size (95% CI) [c]			0.54 (0.32, 0.75)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	13.3	15.6	2.2	33.3	22.2	-11.1
		SD	21.08	17.21	19.79	33.33	19.25	19.25
		95% CI	1.7, 25.0	6.0, 25.1	-8.7, 13.2	-49.5, 116.1	-25.6, 70.0	-58.9, 36.7
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			2.2 (-8.7, 13.2)			-11.1 (-58.9, 36.7)
		P-value [a]			0.670			0.423
		Mean Diff (95% CI) [b]			13.3 (-13.1, 39.8)			
		P-value [b]			0.301			
		Effect Size (95% CI) [c]			0.51 (0.30, 0.73)			
	C23D1	N	11	11	11	3	3	3
		Mean	15.2	21.2	6.1	33.3	33.3	0.0
		SD	22.92	22.47	20.10	33.33	33.33	0.00
		95% CI	-0.2, 30.5	6.1, 36.3	-7.4, 19.6	-49.5, 116.1	-49.5, 116.1	0.0, 0.0
		Median	0.0	33.3	0.0	33.3	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 33.3	0.0, 66.7	0.0, 66.7	0.0, 0.0
		Mean Diff (95% CI) [a]			6.1 (-7.4, 19.6)			0.0 (0.0, 0.0)
		P-value [a]			0.341			NE
		Mean Diff (95% CI) [b]			6.1 (-20.0, 32.1)			
		P-value [b]			0.621			
		Effect Size (95% CI) [c]			0.23 (0.02, 0.45)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	13.3	20.0	6.7	33.3	16.7	-16.7
		SD	23.31	17.21	21.08	47.14	23.57	23.57
		95% CI	-3.3, 30.0	7.7, 32.3	-8.4, 21.7	-390.2, 456.9	-195.1, 228.4	-228.4, 195.1
		Median	0.0	33.3	0.0	33.3	16.7	-16.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			6.7 (-8.4, 21.7)			-16.7 (-228.4, 195.1)
		P-value [a]			0.343			0.500
		Mean Diff (95% CI) [b]			23.3 (-13.5, 60.2)			
		P-value [b]			0.188			
		Effect Size (95% CI) [c]			0.90 (0.68, 1.12)			
	C25D1	N	9	9	9	0	0	0
		Mean	14.8	18.5	3.7	NE	NE	NE
		SD	24.22	17.57	30.93	NE	NE	NE
		95% CI	-3.8, 33.4	5.0, 32.0	-20.1, 27.5	NE, NE	NE, NE	NE, NE
		Median	0.0	33.3	0.0	NE	NE	NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			3.7 (-20.1, 27.5)			NE (NE, NE)
		P-value [a]			0.729			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	4.2	16.7	12.5	0.0	0.0	0.0
		SD	11.79	17.82	17.25	NE	NE	NE
		95% CI	-5.7, 14.0	1.8, 31.6	-1.9, 26.9	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			12.5 (-1.9, 26.9)			0.0 (NE, NE)
		P-value [a]			0.080			NE
		Mean Diff (95% CI) [b]			12.5 (-30.8, 55.8)			
		P-value [b]			0.516			
		Effect Size (95% CI) [c]			0.48 (0.27, 0.70)			
	C27D1	N	8	8	8	1	1	1
		Mean	4.2	16.7	12.5	0.0	0.0	0.0
		SD	11.79	17.82	17.25	NE	NE	NE
		95% CI	-5.7, 14.0	1.8, 31.6	-1.9, 26.9	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			12.5 (-1.9, 26.9)			0.0 (NE, NE)
		P-value [a]			0.080			NE
		Mean Diff (95% CI) [b]			12.5 (-30.8, 55.8)			
		P-value [b]			0.516			
		Effect Size (95% CI) [c]			0.48 (0.27, 0.70)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	4.8	14.3	9.5	0.0	0.0	0.0
		SD	12.60	17.82	16.27	NE	NE	NE
		95% CI	-6.9, 16.4	-2.2, 30.8	-5.5, 24.6	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			9.5 (-5.5, 24.6)			0.0 (NE, NE)
		P-value [a]			0.172			NE
		Mean Diff (95% CI) [b]			9.5 (-33.0, 52.1)			
		P-value [b]			0.604			
		Effect Size (95% CI) [c]			0.37 (0.15, 0.58)			
	C29D1	N	4	4	4	1	1	1
		Mean	8.3	8.3	0.0	0.0	0.0	0.0
		SD	16.67	16.67	0.00	NE	NE	NE
		95% CI	-18.2, 34.9	-18.2, 34.9	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	0.0	8.3	8.3	0.0	33.3	33.3
		SD	0.00	16.67	16.67	NE	NE	NE
		95% CI	0.0, 0.0	-18.2, 34.9	-18.2, 34.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 16.7	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			8.3 (-18.2, 34.9)			33.3 (NE, NE)
		P-value [a]			0.391			NE
		Mean Diff (95% CI) [b]			-25.0 (-84.3, 34.3)			
		P-value [b]			0.272			
		Effect Size (95% CI) [c]			-0.97 (-1.19, -0.74)			
	C31D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	33.3	33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-33.3 (-33.3, -33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-1.29 (-1.52, -1.05)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	33.3	33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-33.3 (-33.3, -33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-1.29 (-1.52, -1.05)			
	C33D1	N	3	3	3	1	1	1
		Mean	0.0	0.0	0.0	0.0	33.3	33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-33.3 (-33.3, -33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-1.29 (-1.52, -1.05)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	0.0	16.7	16.7	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		95% CI	0.0, 0.0	-195.1, 228.4	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	16.7	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	126	126	126
		Mean	18.8	26.5	7.6	19.3	26.7	7.4
		SD	24.84	30.02	26.01	26.45	30.70	29.78
		95% CI	14.5, 23.1	21.3, 31.7	3.1, 12.1	14.6, 24.0	21.3, 32.1	2.2, 12.7
		Median	0.0	33.3	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			7.6 (3.1, 12.1)			7.4 (2.2, 12.7)
		P-value [a]			0.001			0.006
		Mean Diff (95% CI) [b]			0.2 (-6.6, 7.1)			
		P-value [b]			0.948			
		Effect Size (95% CI) [c]			0.01 (-0.20, 0.22)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	11.9	21.4	9.5	22.2	29.6	7.4
		SD	16.57	28.06	24.21	23.57	30.93	32.39
		95% CI	2.3, 21.5	5.2, 37.6	-4.5, 23.5	4.1, 40.3	5.9, 53.4	-17.5, 32.3
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 33.3	0.0, 66.7	-33.3, 66.7	0.0, 66.7	0.0, 100.0	-33.3, 66.7
		Mean Diff (95% CI) [a]			9.5 (-4.5, 23.5)			7.4 (-17.5, 32.3)
		P-value [a]			0.165			0.512
		Mean Diff (95% CI) [b]			2.1 (-22.4, 26.7)			
		P-value [b]			0.859			
		Effect Size (95% CI) [c]			0.08 (-0.13, 0.29)			
Insomnia	Baseline	N	174			164		
		Mean	31.2			35.0		
		SD	31.07			30.18		
		95% CI	26.6, 35.9			30.3, 39.6		
		Median	33.3			33.3		
		Q1, Q3	0.0, 33.3			0.0, 66.7		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

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[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	143	144	143
		Mean	31.1	25.0	-6.1	35.4	33.8	-1.6
		SD	31.09	27.99	25.85	29.66	30.28	31.97
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	26.2, 36.1	20.5, 29.5	-10.3, -2.0	30.5, 40.3	28.8, 38.8	-6.9, 3.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			-6.1 (-10.3, -2.0)			-1.6 (-6.9, 3.7)
		P-value [a]			0.004			0.543
		Mean Diff (95% CI) [b]			-4.5 (-11.2, 2.1)			
		P-value [b]			0.183			
		Effect Size (95% CI) [c]			-0.15 (-0.36, 0.07)			
	C3D1	N	124	124	124	101	102	101
		Mean	32.8	24.2	-8.6	34.7	32.0	-2.6
		SD	30.94	28.93	26.84	28.64	31.79	29.32
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	27.3, 38.3	19.1, 29.3	-13.4, -3.8	29.0, 40.3	25.8, 38.3	-8.4, 3.1
		Q1, Q3	0.0, 66.7	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 66.7	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			-8.6 (-13.4, -3.8)			-2.6 (-8.4, 3.1)
		P-value [a]			0.001			0.368
		Mean Diff (95% CI) [b]			-6.0 (-13.4, 1.4)			
		P-value [b]			0.113			
		Effect Size (95% CI) [c]			-0.19 (-0.41, 0.02)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	33.0	24.7	-8.3	35.1	28.7	-6.4
		SD	30.51	29.25	28.47	28.24	27.04	28.62
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	27.3, 38.7	19.2, 30.2	-13.7, -3.0	29.3, 40.9	23.2, 34.3	-12.2, -0.5
		Q1, Q3	0.0, 66.7	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-8.3 (-13.7, -3.0)			-6.4 (-12.2, -0.5)
		P-value [a]			0.002			0.033
		Mean Diff (95% CI) [b]			-2.0 (-9.8, 5.9)			
		P-value [b]			0.626			
		Effect Size (95% CI) [c]			-0.06 (-0.28, 0.15)			
	C5D1	N	97	97	97	79	79	79
		Mean	34.4	26.1	-8.2	35.9	35.4	-0.4
		SD	30.60	30.13	26.37	28.63	26.33	33.54
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	28.2, 40.5	20.0, 32.2	-13.6, -2.9	29.5, 42.3	29.5, 41.3	-7.9, 7.1
		Q1, Q3	0.0, 66.7	0.0, 33.3	-33.3, 0.0	0.0, 66.7	33.3, 66.7	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 33.3	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-8.2 (-13.6, -2.9)			-0.4 (-7.9, 7.1)
		P-value [a]			0.003			0.911
		Mean Diff (95% CI) [b]			-7.8 (-16.7, 1.1)			
		P-value [b]			0.085			
		Effect Size (95% CI) [c]			-0.25 (-0.47, -0.04)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	95	95	95	69	69	69
		Mean	33.3	21.4	-11.9	36.2	33.3	-2.9
		SD	29.97	27.90	24.27	29.56	28.01	34.65
		Median	33.3	0.0	0.0	33.3	33.3	0.0
		95% CI	27.2, 39.4	15.7, 27.1	-16.9, -7.0	29.1, 43.3	26.6, 40.1	-11.2, 5.4
		Q1, Q3	0.0, 66.7	0.0, 33.3	-33.3, 0.0	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 33.3	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			-11.9 (-16.9, -7.0)			-2.9 (-11.2, 5.4)
		P-value [a]			<.001			0.490
		Mean Diff (95% CI) [b]			-9.0 (-18.1, 0.1)			
		P-value [b]			0.051			
		Effect Size (95% CI) [c]			-0.29 (-0.51, -0.08)			
	C7D1	N	79	79	79	53	53	53
		Mean	32.9	22.4	-10.5	36.5	27.7	-8.8
		SD	30.43	29.10	25.90	28.69	27.53	32.78
		Median	33.3	0.0	0.0	33.3	33.3	0.0
		95% CI	26.1, 39.7	15.8, 28.9	-16.3, -4.7	28.6, 44.4	20.1, 35.3	-17.8, 0.2
		Q1, Q3	0.0, 66.7	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			-10.5 (-16.3, -4.7)			-8.8 (-17.8, 0.2)
		P-value [a]			0.001			0.056
		Mean Diff (95% CI) [b]			-1.7 (-11.9, 8.4)			
		P-value [b]			0.734			
		Effect Size (95% CI) [c]			-0.06 (-0.27, 0.16)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	32.0	21.9	-10.1	38.7	30.7	-8.0
		SD	27.99	30.58	23.74	28.06	29.23	30.54
		Median	33.3	0.0	0.0	33.3	33.3	0.0
		95% CI	25.6, 38.4	14.9, 28.9	-15.5, -4.7	30.7, 46.6	22.4, 39.0	-16.7, 0.7
		Q1, Q3	0.0, 50.0	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-10.1 (-15.5, -4.7)			-8.0 (-16.7, 0.7)
		P-value [a]			<.001			0.070
		Mean Diff (95% CI) [b]			-2.1 (-11.7, 7.5)			
		P-value [b]			0.668			
		Effect Size (95% CI) [c]			-0.07 (-0.28, 0.14)			
	C9D1	N	60	60	60	42	42	42
		Mean	32.2	26.7	-5.6	39.7	29.4	-10.3
		SD	29.41	27.99	26.87	29.67	28.71	31.66
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	24.6, 39.8	19.4, 33.9	-12.5, 1.4	30.4, 48.9	20.4, 38.3	-20.2, -0.5
		Q1, Q3	0.0, 66.7	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-100.0, 33.3
		Mean Diff (95% CI) [a]			-5.6 (-12.5, 1.4)			-10.3 (-20.2, -0.5)
		P-value [a]			0.115			0.041
		Mean Diff (95% CI) [b]			4.8 (-6.8, 16.3)			
		P-value [b]			0.415			
		Effect Size (95% CI) [c]			0.16 (-0.06, 0.37)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	53	53	53	30	30	30
		Mean	32.7	27.0	-5.7	42.2	32.2	-10.0
		SD	28.86	31.39	24.23	30.24	32.14	26.48
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	24.7, 40.7	18.4, 35.7	-12.3, 1.0	30.9, 53.5	20.2, 44.2	-19.9, -0.1
		Q1, Q3	0.0, 66.7	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-5.7 (-12.3, 1.0)			-10.0 (-19.9, -0.1)
		P-value [a]			0.095			0.048
		Mean Diff (95% CI) [b]			4.3 (-7.1, 15.7)			
		P-value [b]			0.451			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.35)			
	C11D1	N	45	45	45	23	23	23
		Mean	34.1	27.4	-6.7	34.8	24.6	-10.1
		SD	29.72	27.79	23.14	25.58	27.00	29.19
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	25.1, 43.0	19.1, 35.8	-13.6, 0.3	23.7, 45.8	13.0, 36.3	-22.8, 2.5
		Q1, Q3	0.0, 66.7	0.0, 33.3	0.0, 0.0	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 33.3	0.0, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-6.7 (-13.6, 0.3)			-10.1 (-22.8, 2.5)
		P-value [a]			0.060			0.110
		Mean Diff (95% CI) [b]			3.5 (-9.5, 16.4)			
		P-value [b]			0.594			
		Effect Size (95% CI) [c]			0.11 (-0.10, 0.33)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	29.3	22.0	-7.3	31.6	19.3	-12.3
		SD	27.08	29.45	22.99	23.50	23.08	27.69
		Median	33.3	0.0	0.0	33.3	0.0	0.0
		95% CI	20.7, 37.8	12.7, 31.2	-14.6, -0.1	20.3, 42.9	8.2, 30.4	-25.6, 1.1
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			-7.3 (-14.6, -0.1)			-12.3 (-25.6, 1.1)
		P-value [a]			0.048			0.069
		Mean Diff (95% CI) [b]			5.0 (-8.7, 18.6)			
		P-value [b]			0.469			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			
	C13D1	N	32	32	32	15	15	15
		Mean	28.1	21.9	-6.2	35.6	15.6	-20.0
		SD	29.46	28.85	21.48	26.63	27.79	27.60
		Median	33.3	0.0	0.0	33.3	0.0	-33.3
		95% CI	17.5, 38.7	11.5, 32.3	-14.0, 1.5	20.8, 50.3	0.2, 30.9	-35.3, -4.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 33.3	0.0, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-6.2 (-14.0, 1.5)			-20.0 (-35.3, -4.7)
		P-value [a]			0.110			0.014
		Mean Diff (95% CI) [b]			13.7 (-1.1, 28.6)			
		P-value [b]			0.069			
		Effect Size (95% CI) [c]			0.45 (0.23, 0.66)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	28.3	18.2	-10.1	38.9	11.1	-27.8
		SD	27.79	28.98	25.66	27.83	29.59	23.92
		Median	33.3	0.0	0.0	33.3	0.0	-33.3
		95% CI	18.4, 38.1	7.9, 28.5	-19.2, -1.0	21.2, 56.6	-7.7, 29.9	-43.0, -12.6
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 50.0	0.0, 0.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 0.0
		Mean Diff (95% CI) [a]			-10.1 (-19.2, -1.0)			-27.8 (-43.0, -12.6)
		P-value [a]			0.031			0.002
		Mean Diff (95% CI) [b]			17.7 (0.5, 34.8)			
		P-value [b]			0.044			
		Effect Size (95% CI) [c]			0.58 (0.36, 0.79)			
	C15D1	N	28	28	28	13	13	13
		Mean	28.6	19.0	-9.5	38.5	33.3	-5.1
		SD	29.70	26.34	28.48	26.69	27.22	22.96
		Median	33.3	0.0	0.0	33.3	33.3	0.0
		95% CI	17.1, 40.1	8.8, 29.3	-20.6, 1.5	22.3, 54.6	16.9, 49.8	-19.0, 8.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	33.3, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 33.3	0.0, 100.0	0.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			-9.5 (-20.6, 1.5)			-5.1 (-19.0, 8.7)
		P-value [a]			0.088			0.436
		Mean Diff (95% CI) [b]			-4.4 (-22.7, 13.9)			
		P-value [b]			0.629			
		Effect Size (95% CI) [c]			-0.14 (-0.36, 0.07)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	27.4	15.5	-11.9	43.3	23.3	-20.0
		SD	25.75	23.10	18.62	27.44	22.50	23.31
		Median	33.3	0.0	0.0	33.3	33.3	-16.7
		95% CI	17.4, 37.4	6.5, 24.4	-19.1, -4.7	23.7, 63.0	7.2, 39.4	-36.7, -3.3
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 33.3	0.0, 100.0	0.0, 66.7	-66.7, 0.0
		Mean Diff (95% CI) [a]			-11.9 (-19.1, -4.7)			-20.0 (-36.7, -3.3)
		P-value [a]			0.002			0.024
		Mean Diff (95% CI) [b]			8.1 (-6.8, 23.0)			
		P-value [b]			0.277			
		Effect Size (95% CI) [c]			0.26 (0.05, 0.48)			
	C17D1	N	26	26	26	7	7	7
		Mean	25.6	20.5	-5.1	52.4	19.0	-33.3
		SD	27.17	28.40	22.49	26.23	26.23	19.25
		Median	33.3	0.0	0.0	33.3	0.0	-33.3
		95% CI	14.7, 36.6	9.0, 32.0	-14.2, 4.0	28.1, 76.6	-5.2, 43.3	-51.1, -15.5
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, -33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 33.3	33.3, 100.0	0.0, 66.7	-66.7, 0.0
		Mean Diff (95% CI) [a]			-5.1 (-14.2, 4.0)			-33.3 (-51.1, -15.5)
		P-value [a]			0.256			0.004
		Mean Diff (95% CI) [b]			28.2 (9.2, 47.2)			
		P-value [b]			0.005			
		Effect Size (95% CI) [c]			0.92 (0.69, 1.14)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	27.3	22.7	-4.5	42.9	23.8	-19.0
		SD	28.43	33.15	23.67	31.71	37.09	26.23
		Median	33.3	0.0	0.0	33.3	0.0	0.0
		95% CI	14.7, 39.9	8.0, 37.4	-15.0, 6.0	13.5, 72.2	-10.5, 58.1	-43.3, 5.2
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 0.0
		Mean Diff (95% CI) [a]			-4.5 (-15.0, 6.0)			-19.0 (-43.3, 5.2)
		P-value [a]			0.378			0.103
		Mean Diff (95% CI) [b]			14.5 (-7.1, 36.1)			
		P-value [b]			0.180			
		Effect Size (95% CI) [c]			0.47 (0.26, 0.69)			
	C19D1	N	20	20	20	6	6	6
		Mean	28.3	21.7	-6.7	33.3	27.8	-5.6
		SD	29.17	31.11	17.44	21.08	13.61	25.09
		Median	33.3	0.0	0.0	33.3	33.3	0.0
		95% CI	14.7, 42.0	7.1, 36.2	-14.8, 1.5	11.2, 55.5	13.5, 42.1	-31.9, 20.8
		Q1, Q3	0.0, 33.3	0.0, 33.3	-16.7, 0.0	33.3, 33.3	33.3, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			-6.7 (-14.8, 1.5)			-5.6 (-31.9, 20.8)
		P-value [a]			0.104			0.611
		Mean Diff (95% CI) [b]			-1.1 (-19.6, 17.4)			
		P-value [b]			0.903			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.18)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	23.3	18.3	-5.0	41.7	16.7	-25.0
		SD	24.42	22.88	19.57	16.67	19.25	16.67
		Median	33.3	0.0	0.0	33.3	16.7	-33.3
		95% CI	11.9, 34.8	7.6, 29.0	-14.2, 4.2	15.1, 68.2	-14.0, 47.3	-51.5, 1.5
		Q1, Q3	0.0, 33.3	0.0, 33.3	-16.7, 0.0	33.3, 50.0	0.0, 33.3	-33.3, -16.7
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 33.3	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			-5.0 (-14.2, 4.2)			-25.0 (-51.5, 1.5)
		P-value [a]			0.267			0.058
		Mean Diff (95% CI) [b]			20.0 (-1.8, 41.8)			
		P-value [b]			0.070			
		Effect Size (95% CI) [c]			0.65 (0.43, 0.87)			
	C21D1	N	18	18	18	4	4	4
		Mean	24.1	22.2	-1.9	41.7	25.0	-16.7
		SD	25.06	25.57	24.18	16.67	16.67	19.25
		Median	33.3	16.7	0.0	33.3	33.3	-16.7
		95% CI	11.6, 36.5	9.5, 34.9	-13.9, 10.2	15.1, 68.2	-1.5, 51.5	-47.3, 14.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	33.3, 50.0	16.7, 33.3	-33.3, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 66.7	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			-1.9 (-13.9, 10.2)			-16.7 (-47.3, 14.0)
		P-value [a]			0.749			0.182
		Mean Diff (95% CI) [b]			14.8 (-12.3, 41.9)			
		P-value [b]			0.268			
		Effect Size (95% CI) [c]			0.48 (0.27, 0.70)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	26.7	24.4	-2.2	44.4	11.1	-33.3
		SD	25.82	26.63	29.46	19.25	19.25	0.00
		Median	33.3	33.3	0.0	33.3	0.0	-33.3
		95% CI	12.4, 41.0	9.7, 39.2	-18.5, 14.1	-3.4, 92.3	-36.7, 58.9	-33.3, -33.3
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 66.7	0.0, 33.3	-33.3, -33.3
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 66.7	33.3, 66.7	0.0, 33.3	-33.3, -33.3
		Mean Diff (95% CI) [a]			-2.2 (-18.5, 14.1)			-33.3 (-33.3, -33.3)
		P-value [a]			0.774			<.001
		Mean Diff (95% CI) [b]			31.1 (-5.8, 68.1)			
		P-value [b]			0.093			
		Effect Size (95% CI) [c]			1.01 (0.79, 1.24)			
	C23D1	N	11	11	11	3	3	3
		Mean	24.2	21.2	-3.0	44.4	22.2	-22.2
		SD	26.21	26.97	17.98	19.25	19.25	19.25
		Median	33.3	0.0	0.0	33.3	33.3	-33.3
		95% CI	6.6, 41.8	3.1, 39.3	-15.1, 9.0	-3.4, 92.3	-25.6, 70.0	-70.0, 25.6
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 33.3	33.3, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			-3.0 (-15.1, 9.0)			-22.2 (-70.0, 25.6)
		P-value [a]			0.588			0.184
		Mean Diff (95% CI) [b]			19.2 (-6.6, 45.0)			
		P-value [b]			0.131			
		Effect Size (95% CI) [c]			0.62 (0.41, 0.84)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	26.7	20.0	-6.7	50.0	33.3	-16.7
		SD	26.29	28.11	21.08	23.57	0.00	23.57
		Median	33.3	0.0	0.0	50.0	33.3	-16.7
		95% CI	7.9, 45.5	-0.1, 40.1	-21.7, 8.4	-161.8, 261.8	33.3, 33.3	-228.4, 195.1
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 66.7	33.3, 33.3	-33.3, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 33.3	33.3, 66.7	33.3, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			-6.7 (-21.7, 8.4)			-16.7 (-228.4, 195.1)
		P-value [a]			0.343			0.500
		Mean Diff (95% CI) [b]			10.0 (-26.8, 46.8)			
		P-value [b]			0.559			
		Effect Size (95% CI) [c]			0.33 (0.11, 0.54)			
	C25D1	N	9	9	9	0	0	0
		Mean	25.9	29.6	3.7	NE	NE	NE
		SD	27.78	35.14	26.06	NE	NE	NE
		Median	33.3	33.3	0.0	NE	NE	NE
		95% CI	4.6, 47.3	2.6, 56.6	-16.3, 23.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			3.7 (-16.3, 23.7)			NE (NE, NE)
		P-value [a]			0.681			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	16.7	8.3	-8.3	33.3	0.0	-33.3
		SD	17.82	15.43	23.57	NE	NE	NE
		Median	16.7	0.0	0.0	33.3	0.0	-33.3
		95% CI	1.8, 31.6	-4.6, 21.2	-28.0, 11.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 16.7	-33.3, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			-8.3 (-28.0, 11.4)			-33.3 (NE, NE)
		P-value [a]			0.351			NE
		Mean Diff (95% CI) [b]			25.0 (-34.1, 84.1)			
		P-value [b]			0.351			
		Effect Size (95% CI) [c]			0.81 (0.59, 1.04)			
	C27D1	N	8	8	8	1	1	1
		Mean	16.7	16.7	0.0	33.3	33.3	0.0
		SD	17.82	17.82	30.86	NE	NE	NE
		Median	16.7	16.7	0.0	33.3	33.3	0.0
		95% CI	1.8, 31.6	1.8, 31.6	-25.8, 25.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 33.3	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (-25.8, 25.8)			0.0 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			0.0 (-77.4, 77.4)			
		P-value [b]			1.000			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	19.0	9.5	-9.5	33.3	33.3	0.0
		SD	17.82	16.27	25.20	NE	NE	NE
		Median	33.3	0.0	0.0	33.3	33.3	0.0
		95% CI	2.6, 35.5	-5.5, 24.6	-32.8, 13.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			-9.5 (-32.8, 13.8)			0.0 (NE, NE)
		P-value [a]			0.356			NE
		Mean Diff (95% CI) [b]			-9.5 (-75.4, 56.4)			
		P-value [b]			0.736			
		Effect Size (95% CI) [c]			-0.31 (-0.52, -0.10)			
	C29D1	N	4	4	4	1	1	1
		Mean	16.7	25.0	8.3	33.3	33.3	0.0
		SD	19.25	16.67	31.91	NE	NE	NE
		Median	16.7	33.3	16.7	33.3	33.3	0.0
		95% CI	-14.0, 47.3	-1.5, 51.5	-42.4, 59.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 33.3	16.7, 33.3	-16.7, 33.3	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			8.3 (-42.4, 59.1)			0.0 (NE, NE)
		P-value [a]			0.638			NE
		Mean Diff (95% CI) [b]			8.3 (-105.2, 121.9)			
		P-value [b]			0.830			
		Effect Size (95% CI) [c]			0.27 (0.06, 0.49)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	25.0	8.3	-16.7	33.3	33.3	0.0
		SD	16.67	16.67	19.25	NE	NE	NE
		Median	33.3	0.0	-16.7	33.3	33.3	0.0
		95% CI	-1.5, 51.5	-18.2, 34.9	-47.3, 14.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	16.7, 33.3	0.0, 16.7	-33.3, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			-16.7 (-47.3, 14.0)			0.0 (NE, NE)
		P-value [a]			0.182			NE
		Mean Diff (95% CI) [b]			-16.7 (-85.1, 51.8)			
		P-value [b]			0.495			
		Effect Size (95% CI) [c]			-0.54 (-0.76, -0.33)			
	C31D1	N	2	2	2	1	1	1
		Mean	33.3	16.7	-16.7	33.3	0.0	-33.3
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	33.3	16.7	-16.7	33.3	0.0	-33.3
		95% CI	33.3, 33.3	-195.1, 228.4	-228.4, 195.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	33.3, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			-16.7 (-228.4, 195.1)			-33.3 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			16.7 (-350.1, 383.5)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			0.54 (0.33, 0.76)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	33.3	16.7	-16.7	33.3	33.3	0.0
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	33.3	16.7	-16.7	33.3	33.3	0.0
		95% CI	33.3, 33.3	-195.1, 228.4	-228.4, 195.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Min, Max	33.3, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			-16.7 (-228.4, 195.1)			0.0 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			-16.7 (-383.5, 350.1)			
		P-value [b]			0.667			
		Effect Size (95% CI) [c]			-0.54 (-0.76, -0.33)			
	C33D1	N	3	3	3	1	1	1
		Mean	33.3	11.1	-22.2	33.3	33.3	0.0
		SD	0.00	19.25	19.25	NE	NE	NE
		Median	33.3	0.0	-33.3	33.3	33.3	0.0
		95% CI	33.3, 33.3	-36.7, 58.9	-70.0, 25.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Min, Max	33.3, 33.3	0.0, 33.3	-33.3, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			-22.2 (-70.0, 25.6)			0.0 (NE, NE)
		P-value [a]			0.184			NE
		Mean Diff (95% CI) [b]			-22.2 (-117.8, 73.4)			
		P-value [b]			0.423			
		Effect Size (95% CI) [c]			-0.72 (-0.94, -0.50)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	33.3	22.2	-11.1	NE	NE	NE
		SD	0.00	38.49	38.49	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	33.3, 33.3	-73.4, 117.8	-106.7, 84.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 66.7	-33.3, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 66.7	-33.3, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-11.1 (-106.7, 84.5)			NE (NE, NE)
		P-value [a]			0.667			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	33.3	16.7	-16.7	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	33.3	16.7	-16.7	NE	NE	NE
		95% CI	33.3, 33.3	-195.1, 228.4	-228.4, 195.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-16.7 (-228.4, 195.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	33.3	11.1	-22.2	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	33.3, 33.3	-36.7, 58.9	-70.0, 25.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-22.2 (-70.0, 25.6)			NE (NE, NE)
		P-value [a]			0.184			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	33.3	11.1	-22.2	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	33.3, 33.3	-36.7, 58.9	-70.0, 25.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-22.2 (-70.0, 25.6)			NE (NE, NE)
		P-value [a]			0.184			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	33.3	0.0	-33.3	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-33.3 (-33.3, -33.3)			NE (NE, NE)
		P-value [a]			<.001			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	33.3	0.0	-33.3	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-33.3 (-33.3, -33.3)			NE (NE, NE)
		P-value [a]			<.001			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	33.3	16.7	-16.7	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	33.3	16.7	-16.7	NE	NE	NE
		95% CI	33.3, 33.3	-195.1, 228.4	-228.4, 195.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 33.3	-33.3, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-16.7 (-228.4, 195.1)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	33.3	0.0	-33.3	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-33.3 (-33.3, -33.3)			NE (NE, NE)
		P-value [a]			<.001			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	33.3	0.0	-33.3	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-33.3 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	33.3	0.0	-33.3	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	33.3	0.0	-33.3	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Min, Max	33.3, 33.3	0.0, 0.0	-33.3, -33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-33.3 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	126	126	126
		Mean	30.8	29.5	-1.3	34.4	32.8	-1.6
		SD	31.38	33.50	31.05	30.97	27.32	31.79
		Median	33.3	33.3	0.0	33.3	33.3	0.0
		95% CI	25.4, 36.2	23.7, 35.3	-6.6, 4.1	28.9, 39.9	28.0, 37.6	-7.2, 4.0
		Q1, Q3	0.0, 33.3	0.0, 66.7	-33.3, 0.0	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			-1.3 (-6.6, 4.1)			-1.6 (-7.2, 4.0)
		P-value [a]			0.640			0.576
		Mean Diff (95% CI) [b]			0.3 (-7.4, 8.0)			
		P-value [b]			0.936			
		Effect Size (95% CI) [c]			0.01 (-0.20, 0.22)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	21.4	21.4	0.0	40.7	40.7	0.0
		SD	28.06	24.83	32.03	43.39	36.43	52.70
		Median	16.7	16.7	0.0	33.3	33.3	0.0
		95% CI	5.2, 37.6	7.1, 35.8	-18.5, 18.5	7.4, 74.1	12.7, 68.7	-40.5, 40.5
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 66.7	0.0, 66.7	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 33.3	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			0.0 (-18.5, 18.5)			0.0 (-40.5, 40.5)
		P-value [a]			1.000			1.000
		Mean Diff (95% CI) [b]			0.0 (-36.6, 36.6)			
		P-value [b]			1.000			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
Appetite Loss	Baseline	N	174			165		
		Mean	18.4			23.0		
		SD	27.18			29.59		
		Median	0.0			0.0		
		95% CI	14.3, 22.5			18.5, 27.6		
		Q1, Q3	0.0, 33.3			0.0, 33.3		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	17.1	23.5	6.4	23.4	25.9	2.5
		SD	26.85	28.41	25.94	30.30	31.65	33.70
		95% CI	12.8, 21.4	18.9, 28.0	2.2, 10.5	18.4, 28.4	20.7, 31.1	-3.0, 8.1
		Median	0.0	0.0	0.0	0.0	16.7	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			6.4 (2.2, 10.5)			2.5 (-3.0, 8.1)
		P-value [a]			0.003			0.366
		Mean Diff (95% CI) [b]			3.8 (-3.0, 10.7)			
		P-value [b]			0.275			
		Effect Size (95% CI) [c]			0.13 (-0.08, 0.35)			
	C3D1	N	123	123	123	102	102	102
		Mean	15.2	20.1	4.9	23.5	21.6	-2.0
		SD	25.34	28.86	30.98	29.51	28.01	33.44
		95% CI	10.7, 19.7	14.9, 25.2	-0.7, 10.4	17.7, 29.3	16.1, 27.1	-8.5, 4.6
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			4.9 (-0.7, 10.4)			-2.0 (-8.5, 4.6)
		P-value [a]			0.083			0.555
		Mean Diff (95% CI) [b]			6.8 (-1.6, 15.3)			
		P-value [b]			0.113			
		Effect Size (95% CI) [c]			0.24 (0.03, 0.45)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	14.6	17.0	2.4	25.2	22.3	-2.8
		SD	25.62	26.09	27.11	29.61	26.95	36.80
		95% CI	9.8, 19.4	12.1, 21.8	-2.7, 7.5	19.1, 31.2	16.8, 27.9	-10.4, 4.7
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			2.4 (-2.7, 7.5)			-2.8 (-10.4, 4.7)
		P-value [a]			0.355			0.457
		Mean Diff (95% CI) [b]			5.2 (-3.6, 14.0)			
		P-value [b]			0.244			
		Effect Size (95% CI) [c]			0.18 (-0.03, 0.40)			
	C5D1	N	96	96	96	80	80	80
		Mean	14.9	13.9	-1.0	24.6	19.6	-5.0
		SD	24.60	24.02	28.39	30.35	28.41	34.41
		95% CI	9.9, 19.9	9.0, 18.8	-6.8, 4.7	17.8, 31.3	13.3, 25.9	-12.7, 2.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			-1.0 (-6.8, 4.7)			-5.0 (-12.7, 2.7)
		P-value [a]			0.720			0.198
		Mean Diff (95% CI) [b]			4.0 (-5.4, 13.3)			
		P-value [b]			0.404			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.35)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	95	95	95	69	69	69
		Mean	13.0	12.6	-0.4	24.6	22.2	-2.4
		SD	23.47	22.38	25.03	30.06	27.81	34.45
		95% CI	8.2, 17.8	8.1, 17.2	-5.4, 4.7	17.4, 31.9	15.5, 28.9	-10.7, 5.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			-0.4 (-5.4, 4.7)			-2.4 (-10.7, 5.9)
		P-value [a]			0.892			0.562
		Mean Diff (95% CI) [b]			2.1 (-7.1, 11.2)			
		P-value [b]			0.657			
		Effect Size (95% CI) [c]			0.07 (-0.14, 0.29)			
	C7D1	N	79	79	79	53	53	53
		Mean	14.3	10.5	-3.8	25.2	13.2	-11.9
		SD	24.85	18.90	23.86	28.42	21.02	29.30
		95% CI	8.8, 19.9	6.3, 14.8	-9.1, 1.5	17.3, 33.0	7.4, 19.0	-20.0, -3.9
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 66.7	0.0, 100.0	0.0, 66.7	-100.0, 33.3
		Mean Diff (95% CI) [a]			-3.8 (-9.1, 1.5)			-11.9 (-20.0, -3.9)
		P-value [a]			0.161			0.005
		Mean Diff (95% CI) [b]			8.2 (-1.0, 17.3)			
		P-value [b]			0.082			
		Effect Size (95% CI) [c]			0.29 (0.07, 0.50)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	15.8	12.7	-3.1	26.0	15.3	-10.7
		SD	26.37	21.06	25.05	28.80	25.39	33.29
		95% CI	9.8, 21.8	7.9, 17.5	-8.8, 2.7	17.8, 34.2	8.1, 22.5	-20.1, -1.2
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			-3.1 (-8.8, 2.7)			-10.7 (-20.1, -1.2)
		P-value [a]			0.289			0.028
		Mean Diff (95% CI) [b]			7.6 (-2.7, 17.9)			
		P-value [b]			0.147			
		Effect Size (95% CI) [c]			0.27 (0.05, 0.48)			
	C9D1	N	60	60	60	42	42	42
		Mean	15.0	13.3	-1.7	26.2	14.3	-11.9
		SD	24.87	22.30	31.55	29.94	23.45	35.17
		95% CI	8.6, 21.4	7.6, 19.1	-9.8, 6.5	16.9, 35.5	7.0, 21.6	-22.9, -0.9
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			-1.7 (-9.8, 6.5)			-11.9 (-22.9, -0.9)
		P-value [a]			0.684			0.034
		Mean Diff (95% CI) [b]			10.2 (-3.0, 23.4)			
		P-value [b]			0.127			
		Effect Size (95% CI) [c]			0.36 (0.15, 0.57)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	15.4	6.2	-9.3	27.8	20.0	-7.8
		SD	25.67	15.96	27.79	29.14	24.13	28.61
		95% CI	8.4, 22.4	1.8, 10.5	-16.8, -1.7	16.9, 38.7	11.0, 29.0	-18.5, 2.9
		Median	0.0	0.0	0.0	33.3	16.7	0.0
		Q1, Q3	0.0, 33.3	0.0, 0.0	-33.3, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			-9.3 (-16.8, -1.7)			-7.8 (-18.5, 2.9)
		P-value [a]			0.018			0.147
		Mean Diff (95% CI) [b]			-1.5 (-14.2, 11.2)			
		P-value [b]			0.817			
		Effect Size (95% CI) [c]			-0.05 (-0.26, 0.16)			
	C11D1	N	45	45	45	23	23	23
		Mean	15.6	10.4	-5.2	23.2	13.0	-10.1
		SD	26.21	17.15	30.11	23.43	19.43	30.87
		95% CI	7.7, 23.4	5.2, 15.5	-14.2, 3.9	13.1, 33.3	4.6, 21.4	-23.5, 3.2
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 33.3	0.0, 66.7	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			-5.2 (-14.2, 3.9)			-10.1 (-23.5, 3.2)
		P-value [a]			0.254			0.129
		Mean Diff (95% CI) [b]			5.0 (-10.6, 20.5)			
		P-value [b]			0.526			
		Effect Size (95% CI) [c]			0.17 (-0.04, 0.39)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	15.4	9.8	-5.7	22.8	8.8	-14.0
		SD	26.97	18.62	28.77	22.37	18.73	25.62
		95% CI	6.9, 24.0	3.9, 15.6	-14.8, 3.4	12.0, 33.6	-0.3, 17.8	-26.4, -1.7
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 33.3	0.0, 66.7	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			-5.7 (-14.8, 3.4)			-14.0 (-26.4, -1.7)
		P-value [a]			0.213			0.028
		Mean Diff (95% CI) [b]			8.3 (-7.1, 23.8)			
		P-value [b]			0.285			
		Effect Size (95% CI) [c]			0.29 (0.08, 0.51)			
	C13D1	N	32	32	32	15	15	15
		Mean	14.6	8.3	-6.3	24.4	4.4	-20.0
		SD	28.00	14.66	32.17	26.63	11.73	24.56
		95% CI	4.5, 24.7	3.0, 13.6	-17.8, 5.3	9.7, 39.2	-2.1, 10.9	-33.6, -6.4
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 0.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 33.3	-100.0, 33.3	0.0, 66.7	0.0, 33.3	-66.7, 0.0
		Mean Diff (95% CI) [a]			-6.3 (-17.8, 5.3)			-20.0 (-33.6, -6.4)
		P-value [a]			0.280			0.007
		Mean Diff (95% CI) [b]			13.7 (-5.2, 32.7)			
		P-value [b]			0.150			
		Effect Size (95% CI) [c]			0.48 (0.27, 0.70)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	14.1	9.1	-5.1	25.0	13.9	-11.1
		SD	27.68	17.23	33.46	25.13	17.16	21.71
		95% CI	4.3, 24.0	3.0, 15.2	-16.9, 6.8	9.0, 41.0	3.0, 24.8	-24.9, 2.7
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 66.7	0.0, 66.7	0.0, 33.3	-66.7, 0.0
		Mean Diff (95% CI) [a]			-5.1 (-16.9, 6.8)			-11.1 (-24.9, 2.7)
		P-value [a]			0.392			0.104
		Mean Diff (95% CI) [b]			6.1 (-14.9, 27.1)			
		P-value [b]			0.563			
		Effect Size (95% CI) [c]			0.21 (0.00, 0.43)			
	C15D1	N	28	28	28	13	13	13
		Mean	15.5	13.1	-2.4	28.2	15.4	-12.8
		SD	29.37	20.96	36.21	26.69	17.30	28.99
		95% CI	4.1, 26.9	5.0, 21.2	-16.4, 11.7	12.1, 44.3	4.9, 25.8	-30.3, 4.7
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 66.7	0.0, 66.7	0.0, 33.3	-66.7, 33.3
		Mean Diff (95% CI) [a]			-2.4 (-16.4, 11.7)			-12.8 (-30.3, 4.7)
		P-value [a]			0.731			0.137
		Mean Diff (95% CI) [b]			10.4 (-12.7, 33.6)			
		P-value [b]			0.368			
		Effect Size (95% CI) [c]			0.37 (0.15, 0.58)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	15.5	10.7	-4.8	26.7	20.0	-6.7
		SD	29.37	22.32	33.60	26.29	17.21	26.29
		95% CI	4.1, 26.9	2.1, 19.4	-17.8, 8.3	7.9, 45.5	7.7, 32.3	-25.5, 12.1
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			-4.8 (-17.8, 8.3)			-6.7 (-25.5, 12.1)
		P-value [a]			0.460			0.443
		Mean Diff (95% CI) [b]			1.9 (-21.9, 25.8)			
		P-value [b]			0.872			
		Effect Size (95% CI) [c]			0.07 (-0.15, 0.28)			
	C17D1	N	26	26	26	7	7	7
		Mean	16.7	9.0	-7.7	28.6	14.3	-14.3
		SD	30.18	20.13	30.27	23.00	17.82	17.82
		95% CI	4.5, 28.9	0.8, 17.1	-19.9, 4.5	7.3, 49.8	-2.2, 30.8	-30.8, 2.2
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 66.7	0.0, 66.7	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			-7.7 (-19.9, 4.5)			-14.3 (-30.8, 2.2)
		P-value [a]			0.207			0.078
		Mean Diff (95% CI) [b]			6.6 (-18.0, 31.2)			
		P-value [b]			0.588			
		Effect Size (95% CI) [c]			0.23 (0.02, 0.45)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	16.7	10.6	-6.1	23.8	14.3	-9.5
		SD	32.12	21.54	37.99	25.20	17.82	31.71
		95% CI	2.4, 30.9	1.1, 20.2	-22.9, 10.8	0.5, 47.1	-2.2, 30.8	-38.8, 19.8
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 66.7	0.0, 66.7	0.0, 33.3	-66.7, 33.3
		Mean Diff (95% CI) [a]			-6.1 (-22.9, 10.8)			-9.5 (-38.8, 19.8)
		P-value [a]			0.463			0.457
		Mean Diff (95% CI) [b]			3.5 (-29.2, 36.1)			
		P-value [b]			0.829			
		Effect Size (95% CI) [c]			0.12 (-0.09, 0.33)			
	C19D1	N	20	20	20	6	6	6
		Mean	18.3	3.3	-15.0	22.2	16.7	-5.6
		SD	33.29	10.26	35.00	27.22	18.26	38.97
		95% CI	2.8, 33.9	-1.5, 8.1	-31.4, 1.4	-6.3, 50.8	-2.5, 35.8	-46.5, 35.3
		Median	0.0	0.0	0.0	16.7	16.7	0.0
		Q1, Q3	0.0, 33.3	0.0, 0.0	-16.7, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 100.0	0.0, 33.3	-100.0, 33.3	0.0, 66.7	0.0, 33.3	-66.7, 33.3
		Mean Diff (95% CI) [a]			-15.0 (-31.4, 1.4)			-5.6 (-46.5, 35.3)
		P-value [a]			0.070			0.741
		Mean Diff (95% CI) [b]			-9.4 (-43.9, 25.0)			
		P-value [b]			0.577			
		Effect Size (95% CI) [c]			-0.33 (-0.55, -0.12)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	18.3	6.7	-11.7	25.0	0.0	-25.0
		SD	33.29	13.68	29.17	31.91	0.00	31.91
		95% CI	2.8, 33.9	0.3, 13.1	-25.3, 2.0	-25.8, 75.8	0.0, 0.0	-75.8, 25.8
		Median	0.0	0.0	0.0	16.7	0.0	-16.7
		Q1, Q3	0.0, 33.3	0.0, 0.0	-16.7, 0.0	0.0, 50.0	0.0, 0.0	-50.0, 0.0
		Min, Max	0.0, 100.0	0.0, 33.3	-100.0, 33.3	0.0, 66.7	0.0, 0.0	-66.7, 0.0
		Mean Diff (95% CI) [a]			-11.7 (-25.3, 2.0)			-25.0 (-75.8, 25.8)
		P-value [a]			0.090			0.215
		Mean Diff (95% CI) [b]			13.3 (-20.2, 46.9)			
		P-value [b]			0.419			
		Effect Size (95% CI) [c]			0.47 (0.25, 0.68)			
	C21D1	N	18	18	18	4	4	4
		Mean	20.4	9.3	-11.1	25.0	25.0	0.0
		SD	34.56	19.15	39.61	31.91	16.67	27.22
		95% CI	3.2, 37.6	-0.3, 18.8	-30.8, 8.6	-25.8, 75.8	-1.5, 51.5	-43.3, 43.3
		Median	0.0	0.0	0.0	16.7	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 50.0	16.7, 33.3	-16.7, 16.7
		Min, Max	0.0, 100.0	0.0, 66.7	-100.0, 33.3	0.0, 66.7	0.0, 33.3	-33.3, 33.3
		Mean Diff (95% CI) [a]			-11.1 (-30.8, 8.6)			0.0 (-43.3, 43.3)
		P-value [a]			0.250			1.000
		Mean Diff (95% CI) [b]			-11.1 (-54.9, 32.7)			
		P-value [b]			0.603			
		Effect Size (95% CI) [c]			-0.39 (-0.61, -0.18)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	11.1	11.1	0.0	33.3	0.0	-33.3
		SD	20.57	24.12	25.20	33.33	0.00	33.33
		95% CI	-0.3, 22.5	-2.2, 24.5	-14.0, 14.0	-49.5, 116.1	0.0, 0.0	-116.1, 49.5
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 66.7	0.0, 0.0	-66.7, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	0.0, 66.7	0.0, 0.0	-66.7, 0.0
		Mean Diff (95% CI) [a]			0.0 (-14.0, 14.0)			-33.3 (-116.1, 49.5)
		P-value [a]			1.000			0.225
		Mean Diff (95% CI) [b]			33.3 (-2.0, 68.7)			
		P-value [b]			0.063			
		Effect Size (95% CI) [c]			1.17 (0.94, 1.40)			
	C23D1	N	11	11	11	3	3	3
		Mean	9.1	15.2	6.1	33.3	0.0	-33.3
		SD	21.56	22.92	20.10	33.33	0.00	33.33
		95% CI	-5.4, 23.6	-0.2, 30.5	-7.4, 19.6	-49.5, 116.1	0.0, 0.0	-116.1, 49.5
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 0.0	-66.7, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 33.3	0.0, 66.7	0.0, 0.0	-66.7, 0.0
		Mean Diff (95% CI) [a]			6.1 (-7.4, 19.6)			-33.3 (-116.1, 49.5)
		P-value [a]			0.341			0.225
		Mean Diff (95% CI) [b]			39.4 (7.0, 71.8)			
		P-value [b]			0.021			
		Effect Size (95% CI) [c]			1.39 (1.15, 1.62)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	10.0	13.3	3.3	33.3	0.0	-33.3
		SD	22.50	23.31	18.92	47.14	0.00	47.14
		95% CI	-6.1, 26.1	-3.3, 30.0	-10.2, 16.9	-390.2, 456.9	0.0, 0.0	-456.9, 390.2
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 66.7	0.0, 0.0	-66.7, 0.0
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 33.3	0.0, 66.7	0.0, 0.0	-66.7, 0.0
		Mean Diff (95% CI) [a]			3.3 (-10.2, 16.9)			-33.3 (-456.9, 390.2)
		P-value [a]			0.591			0.500
		Mean Diff (95% CI) [b]			36.7 (-3.6, 76.9)			
		P-value [b]			0.070			
		Effect Size (95% CI) [c]			1.29 (1.06, 1.52)			
	C25D1	N	9	9	9	0	0	0
		Mean	11.1	11.1	0.0	NE	NE	NE
		SD	23.57	23.57	28.87	NE	NE	NE
		95% CI	-7.0, 29.2	-7.0, 29.2	-22.2, 22.2	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 66.7	0.0, 66.7	-66.7, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (-22.2, 22.2)			NE (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	8.3	16.7	8.3	0.0	0.0	0.0
		SD	23.57	35.63	38.83	NE	NE	NE
		95% CI	-11.4, 28.0	-13.1, 46.5	-24.1, 40.8	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 100.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			8.3 (-24.1, 40.8)			0.0 (NE, NE)
		P-value [a]			0.563			NE
		Mean Diff (95% CI) [b]			8.3 (-89.1, 105.7)			
		P-value [b]			0.845			
		Effect Size (95% CI) [c]			0.29 (0.08, 0.51)			
	C27D1	N	8	8	8	1	1	1
		Mean	8.3	4.2	-4.2	0.0	0.0	0.0
		SD	23.57	11.79	11.79	NE	NE	NE
		95% CI	-11.4, 28.0	-5.7, 14.0	-14.0, 5.7	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-4.2 (-14.0, 5.7)			0.0 (NE, NE)
		P-value [a]			0.351			NE
		Mean Diff (95% CI) [b]			-4.2 (-33.7, 25.4)			
		P-value [b]			0.749			
		Effect Size (95% CI) [c]			-0.15 (-0.36, 0.07)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	9.5	0.0	-9.5	0.0	0.0	0.0
		SD	25.20	0.00	25.20	NE	NE	NE
		95% CI	-13.8, 32.8	0.0, 0.0	-32.8, 13.8	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 0.0	-66.7, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-9.5 (-32.8, 13.8)			0.0 (NE, NE)
		P-value [a]			0.356			NE
		Mean Diff (95% CI) [b]			-9.5 (-75.4, 56.4)			
		P-value [b]			0.736			
		Effect Size (95% CI) [c]			-0.33 (-0.55, -0.12)			
	C29D1	N	4	4	4	1	1	1
		Mean	16.7	8.3	-8.3	0.0	0.0	0.0
		SD	33.33	16.67	41.94	NE	NE	NE
		95% CI	-36.4, 69.7	-18.2, 34.9	-75.1, 58.4	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 16.7	-33.3, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-66.7, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			-8.3 (-75.1, 58.4)			0.0 (NE, NE)
		P-value [a]			0.718			NE
		Mean Diff (95% CI) [b]			-8.3 (-157.6, 140.9)			
		P-value [b]			0.870			
		Effect Size (95% CI) [c]			-0.29 (-0.51, -0.08)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	0.0	0.0	0.0	0.0	33.3	33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-33.3 (-33.3, -33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-1.17 (-1.40, -0.94)			
	C31D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	33.3	33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-33.3 (-33.3, -33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-1.17 (-1.40, -0.94)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	33.3	33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-33.3 (-33.3, -33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-1.17 (-1.40, -0.94)			
	C33D1	N	3	3	3	1	1	1
		Mean	0.0	0.0	0.0	0.0	33.3	33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	0.0	33.3	33.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			-33.3 (-33.3, -33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			-1.17 (-1.40, -0.94)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	126	126	126
		Mean	18.3	24.2	5.9	20.4	25.9	5.6
		SD	27.49	28.96	31.62	27.64	30.08	35.21
		95% CI	13.6, 23.1	19.2, 29.2	0.4, 11.3	15.5, 25.2	20.6, 31.2	-0.7, 11.8
		Median	0.0	33.3	0.0	0.0	33.3	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			5.9 (0.4, 11.3)			5.6 (-0.7, 11.8)
		P-value [a]			0.036			0.079
		Mean Diff (95% CI) [b]			0.3 (-7.9, 8.5)			
		P-value [b]			0.943			
		Effect Size (95% CI) [c]			0.01 (-0.20, 0.22)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	19.0	16.7	-2.4	14.8	33.3	18.5
		SD	31.25	25.32	35.72	24.22	44.10	47.47
		95% CI	1.0, 37.1	2.0, 31.3	-23.0, 18.2	-3.8, 33.4	-0.6, 67.2	-18.0, 55.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 66.7	0.0, 66.7
		Min, Max	0.0, 100.0	0.0, 66.7	-66.7, 66.7	0.0, 66.7	0.0, 100.0	-33.3, 100.0
		Mean Diff (95% CI) [a]			-2.4 (-23.0, 18.2)			18.5 (-18.0, 55.0)
		P-value [a]			0.807			0.276
		Mean Diff (95% CI) [b]			-20.9 (-57.0, 15.2)			
		P-value [b]			0.242			
		Effect Size (95% CI) [c]			-0.73 (-0.95, -0.52)			
Constipation	Baseline	N	174			165		
		Mean	17.6			17.2		
		SD	25.51			26.70		
		95% CI	13.8, 21.4			13.1, 21.3		
		Median	0.0			0.0		
		Q1, Q3	0.0, 33.3			0.0, 33.3		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	17.3	18.9	1.5	17.1	20.1	3.0
		SD	25.44	24.76	26.39	26.44	27.37	26.71
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	13.2, 21.4	14.9, 22.8	-2.7, 5.8	12.8, 21.5	15.6, 24.6	-1.4, 7.4
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			1.5 (-2.7, 5.8)			3.0 (-1.4, 7.4)
		P-value [a]			0.474			0.179
		Mean Diff (95% CI) [b]			-1.5 (-7.6, 4.6)			
		P-value [b]			0.633			
		Effect Size (95% CI) [c]			-0.06 (-0.27, 0.16)			
	C3D1	N	124	124	124	101	101	101
		Mean	17.2	14.8	-2.4	15.5	16.5	1.0
		SD	23.85	23.40	28.88	24.75	25.22	27.27
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	13.0, 21.4	10.6, 18.9	-7.6, 2.7	10.6, 20.4	11.5, 21.5	-4.4, 6.4
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			-2.4 (-7.6, 2.7)			1.0 (-4.4, 6.4)
		P-value [a]			0.353			0.716
		Mean Diff (95% CI) [b]			-3.4 (-10.9, 4.0)			
		P-value [b]			0.367			
		Effect Size (95% CI) [c]			-0.13 (-0.34, 0.08)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	18.5	17.0	-1.5	16.0	15.6	-0.4
		SD	25.64	24.91	29.13	24.31	23.29	22.13
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	13.7, 23.3	12.3, 21.6	-6.9, 4.0	11.0, 20.9	10.8, 20.4	-4.9, 4.2
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-1.5 (-6.9, 4.0)			-0.4 (-4.9, 4.2)
		P-value [a]			0.590			0.877
		Mean Diff (95% CI) [b]			-1.1 (-8.4, 6.1)			
		P-value [b]			0.757			
		Effect Size (95% CI) [c]			-0.04 (-0.26, 0.17)			
	C5D1	N	96	96	96	79	79	79
		Mean	18.4	16.3	-2.1	15.6	17.3	1.7
		SD	25.99	25.13	30.90	24.36	26.07	26.09
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	13.1, 23.7	11.2, 21.4	-8.3, 4.2	10.2, 21.1	11.5, 23.1	-4.2, 7.5
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			-2.1 (-8.3, 4.2)			1.7 (-4.2, 7.5)
		P-value [a]			0.510			0.567
		Mean Diff (95% CI) [b]			-3.8 (-12.4, 4.9)			
		P-value [b]			0.390			
		Effect Size (95% CI) [c]			-0.14 (-0.36, 0.07)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	95	95	95	69	69	69
		Mean	14.7	13.7	-1.1	15.5	15.0	-0.5
		SD	22.13	22.01	28.12	23.28	23.25	26.50
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	10.2, 19.2	9.2, 18.2	-6.8, 4.7	9.9, 21.1	9.4, 20.6	-6.8, 5.9
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-1.1 (-6.8, 4.7)			-0.5 (-6.8, 5.9)
		P-value [a]			0.716			0.880
		Mean Diff (95% CI) [b]			-0.6 (-9.1, 8.0)			
		P-value [b]			0.896			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.19)			
	C7D1	N	79	79	79	53	53	53
		Mean	16.9	11.8	-5.1	13.2	13.8	0.6
		SD	26.08	23.89	33.80	22.01	26.50	27.34
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	11.0, 22.7	6.5, 17.2	-12.6, 2.5	7.1, 19.3	6.5, 21.1	-6.9, 8.2
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 66.7	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-5.1 (-12.6, 2.5)			0.6 (-6.9, 8.2)
		P-value [a]			0.187			0.868
		Mean Diff (95% CI) [b]			-5.7 (-16.7, 5.3)			
		P-value [b]			0.309			
		Effect Size (95% CI) [c]			-0.22 (-0.43, 0.00)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	16.2	15.4	-0.9	14.0	16.0	2.0
		SD	25.24	26.35	33.98	25.28	23.56	28.89
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	10.5, 22.0	9.3, 21.4	-8.6, 6.9	6.8, 21.2	9.3, 22.7	-6.2, 10.2
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-0.9 (-8.6, 6.9)			2.0 (-6.2, 10.2)
		P-value [a]			0.823			0.627
		Mean Diff (95% CI) [b]			-2.9 (-14.4, 8.7)			
		P-value [b]			0.623			
		Effect Size (95% CI) [c]			-0.11 (-0.32, 0.10)			
	C9D1	N	60	60	60	42	42	42
		Mean	15.6	15.0	-0.6	17.5	17.5	0.0
		SD	22.52	24.87	27.10	26.79	25.75	27.55
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	9.7, 21.4	8.6, 21.4	-7.6, 6.4	9.1, 25.8	9.4, 25.5	-8.6, 8.6
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			-0.6 (-7.6, 6.4)			0.0 (-8.6, 8.6)
		P-value [a]			0.874			1.000
		Mean Diff (95% CI) [b]			-0.6 (-11.4, 10.3)			
		P-value [b]			0.920			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.19)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	13.6	19.8	6.2	17.8	17.8	0.0
		SD	19.98	30.04	26.76	27.31	27.31	33.90
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	8.1, 19.0	11.6, 28.0	-1.1, 13.5	7.6, 28.0	7.6, 28.0	-12.7, 12.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			6.2 (-1.1, 13.5)			0.0 (-12.7, 12.7)
		P-value [a]			0.096			1.000
		Mean Diff (95% CI) [b]			6.2 (-7.2, 19.5)			
		P-value [b]			0.361			
		Effect Size (95% CI) [c]			0.24 (0.02, 0.45)			
	C11D1	N	45	45	45	23	23	23
		Mean	11.1	16.3	5.2	18.8	17.4	-1.4
		SD	18.80	30.67	30.11	29.86	24.35	30.94
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	5.5, 16.8	7.1, 25.5	-3.9, 14.2	5.9, 31.8	6.9, 27.9	-14.8, 11.9
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-66.7, 33.3
		Mean Diff (95% CI) [a]			5.2 (-3.9, 14.2)			-1.4 (-14.8, 11.9)
		P-value [a]			0.254			0.824
		Mean Diff (95% CI) [b]			6.6 (-8.9, 22.2)			
		P-value [b]			0.397			
		Effect Size (95% CI) [c]			0.25 (0.04, 0.47)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	10.6	17.1	6.5	17.5	14.0	-3.5
		SD	17.38	24.86	26.05	30.16	23.08	33.14
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	5.1, 16.1	9.2, 24.9	-1.7, 14.7	3.0, 32.1	2.9, 25.2	-19.5, 12.5
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 66.7	-66.7, 66.7
		Mean Diff (95% CI) [a]			6.5 (-1.7, 14.7)			-3.5 (-19.5, 12.5)
		P-value [a]			0.118			0.650
		Mean Diff (95% CI) [b]			10.0 (-5.8, 25.8)			
		P-value [b]			0.210			
		Effect Size (95% CI) [c]			0.38 (0.17, 0.60)			
	C13D1	N	32	32	32	15	15	15
		Mean	9.4	20.8	11.5	22.2	15.6	-6.7
		SD	15.23	27.76	28.85	32.53	17.21	33.81
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	3.9, 14.9	10.8, 30.8	1.1, 21.9	4.2, 40.2	6.0, 25.1	-25.4, 12.1
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 33.3
		Min, Max	0.0, 33.3	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 33.3	-66.7, 33.3
		Mean Diff (95% CI) [a]			11.5 (1.1, 21.9)			-6.7 (-25.4, 12.1)
		P-value [a]			0.032			0.458
		Mean Diff (95% CI) [b]			18.1 (-1.1, 37.3)			
		P-value [b]			0.064			
		Effect Size (95% CI) [c]			0.69 (0.47, 0.91)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	8.1	22.2	14.1	22.2	16.7	-5.6
		SD	14.51	28.46	27.68	32.82	22.47	31.25
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	2.9, 13.2	12.1, 32.3	4.3, 24.0	1.4, 43.1	2.4, 30.9	-25.4, 14.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 16.7
		Min, Max	0.0, 33.3	0.0, 100.0	-33.3, 66.7	0.0, 100.0	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			14.1 (4.3, 24.0)			-5.6 (-25.4, 14.3)
		P-value [a]			0.006			0.551
		Mean Diff (95% CI) [b]			19.7 (0.2, 39.2)			
		P-value [b]			0.047			
		Effect Size (95% CI) [c]			0.75 (0.53, 0.97)			
	C15D1	N	28	28	28	13	13	13
		Mean	7.1	20.2	13.1	25.6	15.4	-10.3
		SD	13.93	27.72	29.17	33.76	22.01	25.04
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	1.7, 12.5	9.5, 31.0	1.8, 24.4	5.2, 46.0	2.1, 28.7	-25.4, 4.9
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			13.1 (1.8, 24.4)			-10.3 (-25.4, 4.9)
		P-value [a]			0.025			0.165
		Mean Diff (95% CI) [b]			23.4 (4.4, 42.3)			
		P-value [b]			0.017			
		Effect Size (95% CI) [c]			0.89 (0.67, 1.12)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	6.0	15.5	9.5	26.7	26.7	0.0
		SD	13.00	19.21	19.99	34.43	30.63	22.22
		Median	0.0	0.0	0.0	16.7	33.3	0.0
		95% CI	0.9, 11.0	8.0, 22.9	1.8, 17.3	2.0, 51.3	4.8, 48.6	-15.9, 15.9
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	-33.3, 66.7	0.0, 100.0	0.0, 100.0	-33.3, 33.3
		Mean Diff (95% CI) [a]			9.5 (1.8, 17.3)			0.0 (-15.9, 15.9)
		P-value [a]			0.018			1.000
		Mean Diff (95% CI) [b]			9.5 (-5.8, 24.9)			
		P-value [b]			0.217			
		Effect Size (95% CI) [c]			0.36 (0.15, 0.58)			
	C17D1	N	26	26	26	7	7	7
		Mean	5.1	15.4	10.3	28.6	23.8	-4.8
		SD	12.26	19.39	20.59	35.63	25.20	23.00
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		95% CI	0.2, 10.1	7.6, 23.2	1.9, 18.6	-4.4, 61.5	0.5, 47.1	-26.0, 16.5
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	-33.3, 66.7	0.0, 100.0	0.0, 66.7	-33.3, 33.3
		Mean Diff (95% CI) [a]			10.3 (1.9, 18.6)			-4.8 (-26.0, 16.5)
		P-value [a]			0.018			0.604
		Mean Diff (95% CI) [b]			15.0 (-3.3, 33.3)			
		P-value [b]			0.104			
		Effect Size (95% CI) [c]			0.57 (0.36, 0.79)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	4.5	22.7	18.2	28.6	19.0	-9.5
		SD	11.71	27.96	26.68	35.63	26.23	25.20
		Median	0.0	16.7	0.0	33.3	0.0	0.0
		95% CI	-0.6, 9.7	10.3, 35.1	6.4, 30.0	-4.4, 61.5	-5.2, 43.3	-32.8, 13.8
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	0.0, 100.0	0.0, 66.7	-33.3, 33.3
		Mean Diff (95% CI) [a]			18.2 (6.4, 30.0)			-9.5 (-32.8, 13.8)
		P-value [a]			0.004			0.356
		Mean Diff (95% CI) [b]			27.7 (4.2, 51.2)			
		P-value [b]			0.022			
		Effect Size (95% CI) [c]			1.06 (0.83, 1.29)			
	C19D1	N	20	20	20	6	6	6
		Mean	5.0	26.7	21.7	33.3	33.3	0.0
		SD	12.21	29.81	31.11	36.51	21.08	29.81
		Median	0.0	33.3	16.7	33.3	33.3	0.0
		95% CI	-0.7, 10.7	12.7, 40.6	7.1, 36.2	-5.0, 71.7	11.2, 55.5	-31.3, 31.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	33.3, 33.3	-33.3, 33.3
		Min, Max	0.0, 33.3	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 66.7	-33.3, 33.3
		Mean Diff (95% CI) [a]			21.7 (7.1, 36.2)			0.0 (-31.3, 31.3)
		P-value [a]			0.006			1.000
		Mean Diff (95% CI) [b]			21.7 (-8.0, 51.3)			
		P-value [b]			0.144			
		Effect Size (95% CI) [c]			0.83 (0.61, 1.05)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	5.0	20.0	15.0	50.0	33.3	-16.7
		SD	12.21	19.94	20.16	33.33	27.22	19.25
		Median	0.0	33.3	0.0	33.3	33.3	-16.7
		95% CI	-0.7, 10.7	10.7, 29.3	5.6, 24.4	-3.0, 103.0	-10.0, 76.6	-47.3, 14.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 66.7	16.7, 50.0	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	33.3, 100.0	0.0, 66.7	-33.3, 0.0
		Mean Diff (95% CI) [a]			15.0 (5.6, 24.4)			-16.7 (-47.3, 14.0)
		P-value [a]			0.004			0.182
		Mean Diff (95% CI) [b]			31.7 (8.9, 54.4)			
		P-value [b]			0.009			
		Effect Size (95% CI) [c]			1.21 (0.98, 1.44)			
	C21D1	N	18	18	18	4	4	4
		Mean	5.6	22.2	16.7	50.0	33.3	-16.7
		SD	12.78	30.25	26.20	33.33	27.22	19.25
		Median	0.0	0.0	0.0	33.3	33.3	-16.7
		95% CI	-0.8, 11.9	7.2, 37.3	3.6, 29.7	-3.0, 103.0	-10.0, 76.6	-47.3, 14.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 66.7	16.7, 50.0	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	33.3, 100.0	0.0, 66.7	-33.3, 0.0
		Mean Diff (95% CI) [a]			16.7 (3.6, 29.7)			-16.7 (-47.3, 14.0)
		P-value [a]			0.015			0.182
		Mean Diff (95% CI) [b]			33.3 (4.2, 62.5)			
		P-value [b]			0.027			
		Effect Size (95% CI) [c]			1.27 (1.04, 1.51)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	4.4	20.0	15.6	33.3	22.2	-11.1
		SD	11.73	24.56	24.77	0.00	19.25	19.25
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		95% CI	-2.1, 10.9	6.4, 33.6	1.8, 29.3	33.3, 33.3	-25.6, 70.0	-58.9, 36.7
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			15.6 (1.8, 29.3)			-11.1 (-58.9, 36.7)
		P-value [a]			0.029			0.423
		Mean Diff (95% CI) [b]			26.7 (-5.7, 59.0)			
		P-value [b]			0.100			
		Effect Size (95% CI) [c]			1.02 (0.79, 1.25)			
	C23D1	N	11	11	11	3	3	3
		Mean	3.0	18.2	15.2	33.3	22.2	-11.1
		SD	10.05	31.14	31.14	0.00	19.25	19.25
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		95% CI	-3.7, 9.8	-2.7, 39.1	-5.8, 36.1	33.3, 33.3	-25.6, 70.0	-58.9, 36.7
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			15.2 (-5.8, 36.1)			-11.1 (-58.9, 36.7)
		P-value [a]			0.138			0.423
		Mean Diff (95% CI) [b]			26.3 (-15.6, 68.1)			
		P-value [b]			0.197			
		Effect Size (95% CI) [c]			1.00 (0.78, 1.23)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	0.0	13.3	13.3	33.3	16.7	-16.7
		SD	0.00	17.21	17.21	0.00	23.57	23.57
		Median	0.0	0.0	0.0	33.3	16.7	-16.7
		95% CI	0.0, 0.0	1.0, 25.6	1.0, 25.6	33.3, 33.3	-195.1, 228.4	-228.4, 195.1
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			13.3 (1.0, 25.6)			-16.7 (-228.4, 195.1)
		P-value [a]			0.037			0.500
		Mean Diff (95% CI) [b]			30.0 (-1.0, 61.0)			
		P-value [b]			0.056			
		Effect Size (95% CI) [c]			1.15 (0.92, 1.38)			
	C25D1	N	9	9	9	0	0	0
		Mean	0.0	25.9	25.9	NE	NE	NE
		SD	0.00	32.39	32.39	NE	NE	NE
		Median	0.0	33.3	33.3	NE	NE	NE
		95% CI	0.0, 0.0	1.0, 50.8	1.0, 50.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 100.0	0.0, 100.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			25.9 (1.0, 50.8)			NE (NE, NE)
		P-value [a]			0.043			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	0.0	12.5	12.5	33.3	0.0	-33.3
		SD	0.00	17.25	17.25	NE	NE	NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		95% CI	0.0, 0.0	-1.9, 26.9	-1.9, 26.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			12.5 (-1.9, 26.9)			-33.3 (NE, NE)
		P-value [a]			0.080			NE
		Mean Diff (95% CI) [b]			45.8 (2.6, 89.1)			
		P-value [b]			0.041			
		Effect Size (95% CI) [c]			1.75 (1.50, 2.00)			
	C27D1	N	8	8	8	1	1	1
		Mean	0.0	8.3	8.3	33.3	0.0	-33.3
		SD	0.00	15.43	15.43	NE	NE	NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		95% CI	0.0, 0.0	-4.6, 21.2	-4.6, 21.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 16.7	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			8.3 (-4.6, 21.2)			-33.3 (NE, NE)
		P-value [a]			0.170			NE
		Mean Diff (95% CI) [b]			41.7 (3.0, 80.4)			
		P-value [b]			0.038			
		Effect Size (95% CI) [c]			1.59 (1.35, 1.84)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	0.0	4.8	4.8	33.3	0.0	-33.3
		SD	0.00	12.60	12.60	NE	NE	NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		95% CI	0.0, 0.0	-6.9, 16.4	-6.9, 16.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			4.8 (-6.9, 16.4)			-33.3 (NE, NE)
		P-value [a]			0.356			NE
		Mean Diff (95% CI) [b]			38.1 (5.1, 71.1)			
		P-value [b]			0.030			
		Effect Size (95% CI) [c]			1.46 (1.22, 1.70)			
	C29D1	N	4	4	4	1	1	1
		Mean	0.0	0.0	0.0	33.3	0.0	-33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			-33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			33.3 (33.3, 33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			1.27 (1.04, 1.51)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	0.0	0.0	0.0	33.3	33.3	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	33.3, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
	C31D1	N	2	2	2	1	1	1
		Mean	0.0	16.7	16.7	33.3	0.0	-33.3
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	0.0	16.7	16.7	33.3	0.0	-33.3
		95% CI	0.0, 0.0	-195.1, 228.4	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			-33.3 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			50.0 (-316.8, 416.8)			
		P-value [b]			0.333			
		Effect Size (95% CI) [c]			1.91 (1.65, 2.17)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	33.3	0.0	-33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			-33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			33.3 (33.3, 33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			1.27 (1.04, 1.51)			
	C33D1	N	3	3	3	1	1	1
		Mean	0.0	0.0	0.0	33.3	0.0	-33.3
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			-33.3 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			33.3 (33.3, 33.3)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			1.27 (1.04, 1.51)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	0.0	16.7	16.7	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		Median	0.0	16.7	16.7	NE	NE	NE
		95% CI	0.0, 0.0	-195.1, 228.4	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	129	129	129	125	125	125
		Mean	17.3	17.6	0.3	18.4	18.4	0.0
		SD	25.72	28.28	30.48	27.58	28.85	28.40
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	12.8, 21.8	12.6, 22.5	-5.1, 5.6	13.5, 23.3	13.3, 23.5	-5.0, 5.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			0.3 (-5.1, 5.6)			0.0 (-5.0, 5.0)
		P-value [a]			0.923			1.000
		Mean Diff (95% CI) [b]			0.3 (-7.0, 7.5)			
		P-value [b]			0.944			
		Effect Size (95% CI) [c]			0.01 (-0.20, 0.22)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	14.3	28.6	14.3	14.8	37.0	22.2
		SD	21.54	31.64	25.20	17.57	35.14	47.14
		Median	0.0	16.7	0.0	0.0	33.3	0.0
		95% CI	1.8, 26.7	10.3, 46.8	-0.3, 28.8	1.3, 28.3	10.0, 64.0	-14.0, 58.5
		Q1, Q3	0.0, 33.3	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 66.7
		Min, Max	0.0, 66.7	0.0, 66.7	-33.3, 66.7	0.0, 33.3	0.0, 100.0	-33.3, 100.0
		Mean Diff (95% CI) [a]			14.3 (-0.3, 28.8)			22.2 (-14.0, 58.5)
		P-value [a]			0.054			0.195
		Mean Diff (95% CI) [b]			-7.9 (-39.2, 23.3)			
		P-value [b]			0.603			
		Effect Size (95% CI) [c]			-0.30 (-0.52, -0.09)			
Diarrhea	Baseline	N	174			165		
		Mean	8.4			9.3		
		SD	18.77			18.98		
		Median	0.0			0.0		
		95% CI	5.6, 11.2			6.4, 12.2		
		Q1, Q3	0.0, 0.0			0.0, 0.0		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	144	144	144
		Mean	7.9	21.5	13.6	10.2	9.0	-1.2
		SD	18.69	30.31	31.95	19.82	19.00	23.79
		95% CI	4.9, 10.9	16.6, 26.3	8.5, 18.7	6.9, 13.4	5.9, 12.2	-5.1, 2.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			13.6 (8.5, 18.7)			-1.2 (-5.1, 2.8)
		P-value [a]			<.001			0.560
		Mean Diff (95% CI) [b]			14.8 (8.3, 21.2)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			0.78 (0.56, 1.00)			
	C3D1	N	123	123	123	101	101	101
		Mean	7.9	23.8	16.0	11.2	8.9	-2.3
		SD	19.13	31.51	33.43	21.23	16.93	22.24
		95% CI	4.4, 11.3	18.2, 29.5	10.0, 22.0	7.0, 15.4	5.6, 12.3	-6.7, 2.1
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 66.7	-100.0, 33.3
		Mean Diff (95% CI) [a]			16.0 (10.0, 22.0)			-2.3 (-6.7, 2.1)
		P-value [a]			<.001			0.299
		Mean Diff (95% CI) [b]			18.3 (10.6, 26.0)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			0.97 (0.74, 1.19)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	9.2	23.2	14.0	12.1	9.2	-2.8
		SD	20.11	28.59	33.07	21.22	17.22	20.54
		95% CI	5.5, 13.0	17.9, 28.6	7.8, 20.2	7.7, 16.4	5.7, 12.7	-7.0, 1.4
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 66.7	-100.0, 66.7
		Mean Diff (95% CI) [a]			14.0 (7.8, 20.2)			-2.8 (-7.0, 1.4)
		P-value [a]			<.001			0.184
		Mean Diff (95% CI) [b]			16.8 (9.1, 24.6)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			0.89 (0.67, 1.11)			
	C5D1	N	98	98	98	80	80	80
		Mean	7.8	22.8	15.0	12.9	10.4	-2.5
		SD	17.78	28.96	32.86	21.54	18.82	21.07
		95% CI	4.3, 11.4	17.0, 28.6	8.4, 21.6	8.1, 17.7	6.2, 14.6	-7.2, 2.2
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 66.7	-66.7, 66.7
		Mean Diff (95% CI) [a]			15.0 (8.4, 21.6)			-2.5 (-7.2, 2.2)
		P-value [a]			<.001			0.292
		Mean Diff (95% CI) [b]			17.5 (9.1, 25.8)			
		P-value [b]			<.001			
		Effect Size (95% CI) [c]			0.92 (0.70, 1.15)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	68	68	68
		Mean	7.6	18.7	11.1	13.2	9.3	-3.9
		SD	18.40	26.85	31.22	21.66	16.13	20.39
		95% CI	3.9, 11.4	13.3, 24.2	4.8, 17.4	8.0, 18.5	5.4, 13.2	-8.9, 1.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 66.7	-100.0, 33.3
		Mean Diff (95% CI) [a]			11.1 (4.8, 17.4)			-3.9 (-8.9, 1.0)
		P-value [a]			0.001			0.117
		Mean Diff (95% CI) [b]			15.0 (6.5, 23.6)			
		P-value [b]			0.001			
		Effect Size (95% CI) [c]			0.79 (0.57, 1.02)			
	C7D1	N	79	79	79	52	52	52
		Mean	11.0	18.6	7.6	15.4	8.3	-7.1
		SD	22.47	23.72	28.22	24.22	18.52	21.22
		95% CI	5.9, 16.0	13.3, 23.9	1.3, 13.9	8.6, 22.1	3.2, 13.5	-13.0, -1.1
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 66.7	0.0, 100.0	0.0, 66.7	-100.0, 66.7
		Mean Diff (95% CI) [a]			7.6 (1.3, 13.9)			-7.1 (-13.0, -1.1)
		P-value [a]			0.019			0.020
		Mean Diff (95% CI) [b]			14.6 (5.6, 23.7)			
		P-value [b]			0.002			
		Effect Size (95% CI) [c]			0.77 (0.55, 0.99)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	75	75	75	50	50	50
		Mean	11.1	18.7	7.6	16.0	8.0	-8.0
		SD	22.81	26.42	34.47	24.50	17.25	23.87
		95% CI	5.9, 16.4	12.6, 24.7	-0.4, 15.5	9.0, 23.0	3.1, 12.9	-14.8, -1.2
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 100.0	0.0, 66.7	-66.7, 66.7
		Mean Diff (95% CI) [a]			7.6 (-0.4, 15.5)			-8.0 (-14.8, -1.2)
		P-value [a]			0.062			0.022
		Mean Diff (95% CI) [b]			15.6 (4.5, 26.6)			
		P-value [b]			0.006			
		Effect Size (95% CI) [c]			0.82 (0.60, 1.04)			
	C9D1	N	59	59	59	42	42	42
		Mean	12.4	18.6	6.2	15.9	13.5	-2.4
		SD	23.89	24.97	30.62	24.68	27.60	30.70
		95% CI	6.2, 18.7	12.1, 25.2	-1.8, 14.2	8.2, 23.6	4.9, 22.1	-11.9, 7.2
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			6.2 (-1.8, 14.2)			-2.4 (-11.9, 7.2)
		P-value [a]			0.124			0.618
		Mean Diff (95% CI) [b]			8.6 (-3.7, 20.9)			
		P-value [b]			0.168			
		Effect Size (95% CI) [c]			0.45 (0.24, 0.67)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	11.7	22.2	10.5	17.8	12.2	-5.6
		SD	23.49	28.22	34.76	22.71	23.95	27.80
		95% CI	5.3, 18.1	14.5, 29.9	1.0, 20.0	9.3, 26.3	3.3, 21.2	-15.9, 4.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 66.7	0.0, 100.0	-66.7, 100.0
		Mean Diff (95% CI) [a]			10.5 (1.0, 20.0)			-5.6 (-15.9, 4.8)
		P-value [a]			0.031			0.283
		Mean Diff (95% CI) [b]			16.0 (1.3, 30.8)			
		P-value [b]			0.033			
		Effect Size (95% CI) [c]			0.85 (0.63, 1.07)			
	C11D1	N	45	45	45	23	23	23
		Mean	11.9	17.0	5.2	17.4	8.7	-8.7
		SD	24.78	26.23	33.30	22.18	18.03	18.03
		95% CI	4.4, 19.3	9.2, 24.9	-4.8, 15.2	7.8, 27.0	0.9, 16.5	-16.5, -0.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 66.7	0.0, 66.7	-66.7, 0.0
		Mean Diff (95% CI) [a]			5.2 (-4.8, 15.2)			-8.7 (-16.5, -0.9)
		P-value [a]			0.302			0.030
		Mean Diff (95% CI) [b]			13.9 (-1.0, 28.8)			
		P-value [b]			0.067			
		Effect Size (95% CI) [c]			0.73 (0.51, 0.95)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	12.2	16.3	4.1	17.5	8.8	-8.8
		SD	25.56	24.86	34.31	23.22	18.73	24.45
		95% CI	4.1, 20.3	8.4, 24.1	-6.8, 14.9	6.4, 28.7	-0.3, 17.8	-20.6, 3.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-100.0, 100.0	0.0, 66.7	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			4.1 (-6.8, 14.9)			-8.8 (-20.6, 3.0)
		P-value [a]			0.453			0.135
		Mean Diff (95% CI) [b]			12.8 (-4.7, 30.4)			
		P-value [b]			0.148			
		Effect Size (95% CI) [c]			0.68 (0.46, 0.90)			
	C13D1	N	33	33	33	15	15	15
		Mean	9.1	24.2	15.2	15.6	6.7	-8.9
		SD	20.87	27.98	30.15	21.33	13.80	23.46
		95% CI	1.7, 16.5	14.3, 34.2	4.5, 25.8	3.7, 27.4	-1.0, 14.3	-21.9, 4.1
		Median	0.0	33.3	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 100.0	0.0, 66.7	0.0, 33.3	-66.7, 33.3
		Mean Diff (95% CI) [a]			15.2 (4.5, 25.8)			-8.9 (-21.9, 4.1)
		P-value [a]			0.007			0.164
		Mean Diff (95% CI) [b]			24.0 (6.3, 41.8)			
		P-value [b]			0.009			
		Effect Size (95% CI) [c]			1.27 (1.04, 1.50)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	9.1	20.2	11.1	16.7	11.1	-5.6
		SD	20.87	24.92	23.07	22.47	16.41	23.92
		95% CI	1.7, 16.5	11.4, 29.0	2.9, 19.3	2.4, 30.9	0.7, 21.5	-20.8, 9.6
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 66.7	0.0, 66.7	0.0, 33.3	-66.7, 33.3
		Mean Diff (95% CI) [a]			11.1 (2.9, 19.3)			-5.6 (-20.8, 9.6)
		P-value [a]			0.009			0.438
		Mean Diff (95% CI) [b]			16.7 (0.8, 32.5)			
		P-value [b]			0.040			
		Effect Size (95% CI) [c]			0.88 (0.66, 1.10)			
	C15D1	N	28	28	28	13	13	13
		Mean	10.7	25.0	14.3	15.4	12.8	-2.6
		SD	22.32	29.57	33.25	22.01	21.68	28.74
		95% CI	2.1, 19.4	13.5, 36.5	1.4, 27.2	2.1, 28.7	-0.3, 25.9	-19.9, 14.8
		Median	0.0	16.7	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 100.0	0.0, 66.7	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			14.3 (1.4, 27.2)			-2.6 (-19.9, 14.8)
		P-value [a]			0.031			0.753
		Mean Diff (95% CI) [b]			16.8 (-4.8, 38.5)			
		P-value [b]			0.124			
		Effect Size (95% CI) [c]			0.89 (0.67, 1.11)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	9.5	28.6	19.0	13.3	10.0	-3.3
		SD	21.96	31.05	35.63	17.21	22.50	18.92
		95% CI	1.0, 18.0	16.5, 40.6	5.2, 32.9	1.0, 25.6	-6.1, 26.1	-16.9, 10.2
		Median	0.0	33.3	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 100.0	0.0, 33.3	0.0, 66.7	-33.3, 33.3
		Mean Diff (95% CI) [a]			19.0 (5.2, 32.9)			-3.3 (-16.9, 10.2)
		P-value [a]			0.009			0.591
		Mean Diff (95% CI) [b]			22.4 (-1.7, 46.5)			
		P-value [b]			0.068			
		Effect Size (95% CI) [c]			1.18 (0.95, 1.41)			
	C17D1	N	26	26	26	7	7	7
		Mean	10.3	17.9	7.7	14.3	4.8	-9.5
		SD	22.65	25.35	27.17	17.82	12.60	16.27
		95% CI	1.1, 19.4	7.7, 28.2	-3.3, 18.7	-2.2, 30.8	-6.9, 16.4	-24.6, 5.5
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	-33.3, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 100.0	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			7.7 (-3.3, 18.7)			-9.5 (-24.6, 5.5)
		P-value [a]			0.161			0.172
		Mean Diff (95% CI) [b]			17.2 (-4.9, 39.3)			
		P-value [b]			0.122			
		Effect Size (95% CI) [c]			0.91 (0.69, 1.13)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	12.1	15.2	3.0	9.5	4.8	-4.8
		SD	24.22	22.37	22.79	16.27	12.60	12.60
		95% CI	1.4, 22.9	5.2, 25.1	-7.1, 13.1	-5.5, 24.6	-6.9, 16.4	-16.4, 6.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-33.3, 66.7	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			3.0 (-7.1, 13.1)			-4.8 (-16.4, 6.9)
		P-value [a]			0.540			0.356
		Mean Diff (95% CI) [b]			7.8 (-10.9, 26.5)			
		P-value [b]			0.399			
		Effect Size (95% CI) [c]			0.41 (0.20, 0.63)			
	C19D1	N	20	20	20	6	6	6
		Mean	13.3	16.7	3.3	11.1	5.6	-5.6
		SD	25.13	20.23	21.36	17.21	13.61	13.61
		95% CI	1.6, 25.1	7.2, 26.1	-6.7, 13.3	-7.0, 29.2	-8.7, 19.8	-19.8, 8.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 16.7	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 66.7	-33.3, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			3.3 (-6.7, 13.3)			-5.6 (-19.8, 8.7)
		P-value [a]			0.494			0.363
		Mean Diff (95% CI) [b]			8.9 (-10.3, 28.1)			
		P-value [b]			0.349			
		Effect Size (95% CI) [c]			0.47 (0.25, 0.69)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	19	19	19	4	4	4
		Mean	14.0	17.5	3.5	16.7	16.7	0.0
		SD	25.62	25.74	18.90	19.25	19.25	0.00
		95% CI	1.7, 26.4	5.1, 30.0	-5.6, 12.6	-14.0, 47.3	-14.0, 47.3	0.0, 0.0
		Median	0.0	0.0	0.0	16.7	16.7	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			3.5 (-5.6, 12.6)			0.0 (0.0, 0.0)
		P-value [a]			0.429			NE
		Mean Diff (95% CI) [b]			3.5 (-16.5, 23.5)			
		P-value [b]			0.719			
		Effect Size (95% CI) [c]			0.19 (-0.03, 0.40)			
	C21D1	N	18	18	18	4	4	4
		Mean	14.8	16.7	1.9	16.7	8.3	-8.3
		SD	26.13	26.20	17.98	19.25	16.67	16.67
		95% CI	1.8, 27.8	3.6, 29.7	-7.1, 10.8	-14.0, 47.3	-18.2, 34.9	-34.9, 18.2
		Median	0.0	0.0	0.0	16.7	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 16.7	-16.7, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			1.9 (-7.1, 10.8)			-8.3 (-34.9, 18.2)
		P-value [a]			0.668			0.391
		Mean Diff (95% CI) [b]			10.2 (-10.3, 30.7)			
		P-value [b]			0.313			
		Effect Size (95% CI) [c]			0.54 (0.32, 0.75)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

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[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	11.1	17.8	6.7	22.2	11.1	-11.1
		SD	16.27	21.33	25.82	19.25	19.25	19.25
		95% CI	2.1, 20.1	6.0, 29.6	-7.6, 21.0	-25.6, 70.0	-36.7, 58.9	-58.9, 36.7
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	-33.3, 66.7	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			6.7 (-7.6, 21.0)			-11.1 (-58.9, 36.7)
		P-value [a]			0.334			0.423
		Mean Diff (95% CI) [b]			17.8 (-15.9, 51.4)			
		P-value [b]			0.279			
		Effect Size (95% CI) [c]			0.94 (0.72, 1.16)			
	C23D1	N	11	11	11	3	3	3
		Mean	15.2	15.2	0.0	22.2	11.1	-11.1
		SD	17.41	17.41	25.82	19.25	19.25	19.25
		95% CI	3.5, 26.8	3.5, 26.8	-17.3, 17.3	-25.6, 70.0	-36.7, 58.9	-58.9, 36.7
		Median	0.0	0.0	0.0	33.3	0.0	0.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			0.0 (-17.3, 17.3)			-11.1 (-58.9, 36.7)
		P-value [a]			1.000			0.423
		Mean Diff (95% CI) [b]			11.1 (-24.1, 46.4)			
		P-value [b]			0.505			
		Effect Size (95% CI) [c]			0.59 (0.37, 0.80)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	10.0	20.0	10.0	33.3	16.7	-16.7
		SD	16.10	28.11	16.10	0.00	23.57	23.57
		95% CI	-1.5, 21.5	-0.1, 40.1	-1.5, 21.5	33.3, 33.3	-195.1, 228.4	-228.4, 195.1
		Median	0.0	0.0	0.0	33.3	16.7	-16.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	0.0, 33.3	33.3, 33.3	0.0, 33.3	-33.3, 0.0
		Mean Diff (95% CI) [a]			10.0 (-1.5, 21.5)			-16.7 (-228.4, 195.1)
		P-value [a]			0.081			0.500
		Mean Diff (95% CI) [b]			26.7 (-2.7, 56.0)			
		P-value [b]			0.070			
		Effect Size (95% CI) [c]			1.41 (1.17, 1.65)			
	C25D1	N	9	9	9	0	0	0
		Mean	11.1	18.5	7.4	NE	NE	NE
		SD	16.67	17.57	22.22	NE	NE	NE
		95% CI	-1.7, 23.9	5.0, 32.0	-9.7, 24.5	NE, NE	NE, NE	NE, NE
		Median	0.0	33.3	0.0	NE	NE	NE
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			7.4 (-9.7, 24.5)			NE (NE, NE)
		P-value [a]			0.347			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	8.3	29.2	20.8	33.3	0.0	-33.3
		SD	15.43	33.03	35.36	NE	NE	NE
		95% CI	-4.6, 21.2	1.5, 56.8	-8.7, 50.4	NE, NE	NE, NE	NE, NE
		Median	0.0	33.3	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 33.3	0.0, 100.0	0.0, 100.0	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			20.8 (-8.7, 50.4)			-33.3 (NE, NE)
		P-value [a]			0.140			NE
		Mean Diff (95% CI) [b]			54.2 (-34.5, 142.8)			
		P-value [b]			0.192			
		Effect Size (95% CI) [c]			2.86 (2.56, 3.17)			
	C27D1	N	8	8	8	1	1	1
		Mean	8.3	20.8	12.5	33.3	0.0	-33.3
		SD	15.43	24.80	24.80	NE	NE	NE
		95% CI	-4.6, 21.2	0.1, 41.6	-8.2, 33.2	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 16.7	0.0, 33.3	0.0, 16.7	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			12.5 (-8.2, 33.2)			-33.3 (NE, NE)
		P-value [a]			0.197			NE
		Mean Diff (95% CI) [b]			45.8 (-16.4, 108.0)			
		P-value [b]			0.125			
		Effect Size (95% CI) [c]			2.42 (2.14, 2.70)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	4.8	19.0	14.3	33.3	0.0	-33.3
		SD	12.60	17.82	17.82	NE	NE	NE
		95% CI	-6.9, 16.4	2.6, 35.5	-2.2, 30.8	NE, NE	NE, NE	NE, NE
		Median	0.0	33.3	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			14.3 (-2.2, 30.8)			-33.3 (NE, NE)
		P-value [a]			0.078			NE
		Mean Diff (95% CI) [b]			47.6 (1.0, 94.2)			
		P-value [b]			0.047			
		Effect Size (95% CI) [c]			2.52 (2.23, 2.80)			
	C29D1	N	4	4	4	1	1	1
		Mean	8.3	25.0	16.7	33.3	0.0	-33.3
		SD	16.67	31.91	33.33	NE	NE	NE
		95% CI	-18.2, 34.9	-25.8, 75.8	-36.4, 69.7	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 16.7	0.0, 50.0	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			16.7 (-36.4, 69.7)			-33.3 (NE, NE)
		P-value [a]			0.391			NE
		Mean Diff (95% CI) [b]			50.0 (-68.6, 168.6)			
		P-value [b]			0.272			
		Effect Size (95% CI) [c]			2.64 (2.35, 2.93)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	0.0	8.3	8.3	33.3	0.0	-33.3
		SD	0.00	16.67	16.67	NE	NE	NE
		95% CI	0.0, 0.0	-18.2, 34.9	-18.2, 34.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 16.7	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			8.3 (-18.2, 34.9)			-33.3 (NE, NE)
		P-value [a]			0.391			NE
		Mean Diff (95% CI) [b]			41.7 (-17.6, 101.0)			
		P-value [b]			0.111			
		Effect Size (95% CI) [c]			2.20 (1.93, 2.47)			
	C31D1	N	2	2	2	1	1	1
		Mean	0.0	16.7	16.7	33.3	0.0	-33.3
		SD	0.00	23.57	23.57	NE	NE	NE
		95% CI	0.0, 0.0	-195.1, 228.4	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	16.7	33.3	0.0	-33.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			-33.3 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			50.0 (-316.8, 416.8)			
		P-value [b]			0.333			
		Effect Size (95% CI) [c]			2.64 (2.35, 2.93)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	0.0	16.7	16.7	33.3	0.0	-33.3
		SD	0.00	23.57	23.57	NE	NE	NE
		95% CI	0.0, 0.0	-195.1, 228.4	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	16.7	33.3	0.0	-33.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			-33.3 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			50.0 (-316.8, 416.8)			
		P-value [b]			0.333			
		Effect Size (95% CI) [c]			2.64 (2.35, 2.93)			
	C33D1	N	3	3	3	1	1	1
		Mean	0.0	11.1	11.1	33.3	0.0	-33.3
		SD	0.00	19.25	19.25	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	33.3	0.0	-33.3
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	33.3, 33.3	0.0, 0.0	-33.3, -33.3
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			-33.3 (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			44.4 (-51.2, 140.1)			
		P-value [b]			0.184			
		Effect Size (95% CI) [c]			2.35 (2.07, 2.63)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	0.0	22.2	22.2	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		95% CI	0.0, 0.0	-25.6, 70.0	-25.6, 70.0	NE, NE	NE, NE	NE, NE
		Median	0.0	33.3	33.3	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			22.2 (-25.6, 70.0)			NE (NE, NE)
		P-value [a]			0.184			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	0.0	16.7	16.7	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		95% CI	0.0, 0.0	-195.1, 228.4	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	16.7	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	0.0	11.1	11.1	NE	NE	NE
		SD	0.00	19.25	19.25	NE	NE	NE
		95% CI	0.0, 0.0	-36.7, 58.9	-36.7, 58.9	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.1 (-36.7, 58.9)			NE (NE, NE)
		P-value [a]			0.423			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	0.0	16.7	16.7	NE	NE	NE
		SD	0.00	23.57	23.57	NE	NE	NE
		95% CI	0.0, 0.0	-195.1, 228.4	-195.1, 228.4	NE, NE	NE, NE	NE, NE
		Median	0.0	16.7	16.7	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			16.7 (-195.1, 228.4)			NE (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Median	0.0	0.0	0.0	NE	NE	NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	130	130	130	125	125	125
		Mean	7.9	16.4	8.5	8.5	7.7	-0.8
		SD	17.01	26.33	29.73	18.41	15.34	19.61
		95% CI	5.0, 10.9	11.8, 21.0	3.3, 13.6	5.3, 11.8	5.0, 10.4	-4.3, 2.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 66.7	-66.7, 66.7
		Mean Diff (95% CI) [a]			8.5 (3.3, 13.6)			-0.8 (-4.3, 2.7)
		P-value [a]			0.001			0.649
		Mean Diff (95% CI) [b]			9.3 (3.0, 15.5)			
		P-value [b]			0.004			
		Effect Size (95% CI) [c]			0.49 (0.27, 0.71)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	4.8	7.1	2.4	22.2	37.0	14.8
		SD	12.10	19.30	24.33	23.57	30.93	29.40
		95% CI	-2.2, 11.8	-4.0, 18.3	-11.7, 16.4	4.1, 40.3	13.3, 60.8	-7.8, 37.4
		Median	0.0	0.0	0.0	33.3	33.3	0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 33.3	33.3, 33.3	0.0, 33.3
		Min, Max	0.0, 33.3	0.0, 66.7	-33.3, 66.7	0.0, 66.7	0.0, 100.0	-33.3, 66.7
		Mean Diff (95% CI) [a]			2.4 (-11.7, 16.4)			14.8 (-7.8, 37.4)
		P-value [a]			0.720			0.169
		Mean Diff (95% CI) [b]			-12.4 (-35.9, 11.0)			
		P-value [b]			0.282			
		Effect Size (95% CI) [c]			-0.66 (-0.88, -0.44)			
Financial Difficulties	Baseline	N	173			164		
		Mean	13.7			17.5		
		SD	23.55			28.23		
		95% CI	10.1, 17.2			13.1, 21.8		
		Median	0.0			0.0		
		Q1, Q3	0.0, 33.3			0.0, 33.3		
		Min, Max	0.0, 100.0			0.0, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	151	152	151	144	144	144
		Mean	13.5	11.6	-1.8	16.7	12.7	-3.9
		SD	23.47	22.12	19.55	27.03	22.30	22.12
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	9.7, 17.2	8.1, 15.2	-4.9, 1.4	12.2, 21.1	9.1, 16.4	-7.6, -0.3
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			-1.8 (-4.9, 1.4)			-3.9 (-7.6, -0.3)
		P-value [a]			0.269			0.035
		Mean Diff (95% CI) [b]			2.2 (-2.6, 6.9)			
		P-value [b]			0.372			
		Effect Size (95% CI) [c]			0.08 (-0.13, 0.30)			
	C3D1	N	121	122	121	99	100	99
		Mean	11.8	12.8	1.1	16.5	10.7	-5.7
		SD	21.88	25.15	21.91	28.72	22.66	23.35
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	7.9, 15.8	8.3, 17.3	-2.8, 5.0	10.8, 22.2	6.2, 15.2	-10.4, -1.1
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 66.7
		Mean Diff (95% CI) [a]			1.1 (-2.8, 5.0)			-5.7 (-10.4, -1.1)
		P-value [a]			0.581			0.017
		Mean Diff (95% CI) [b]			6.8 (0.8, 12.9)			
		P-value [b]			0.027			
		Effect Size (95% CI) [c]			0.26 (0.05, 0.48)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	110	111	110	93	94	93
		Mean	13.6	10.2	-3.3	15.8	11.0	-4.7
		SD	23.59	20.98	21.63	28.48	22.61	20.61
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	9.2, 18.1	6.3, 14.2	-7.4, 0.8	9.9, 21.6	6.4, 15.6	-8.9, -0.4
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 33.3
		Mean Diff (95% CI) [a]			-3.3 (-7.4, 0.8)			-4.7 (-8.9, -0.4)
		P-value [a]			0.109			0.032
		Mean Diff (95% CI) [b]			1.3 (-4.6, 7.2)			
		P-value [b]			0.657			
		Effect Size (95% CI) [c]			0.05 (-0.16, 0.26)			
	C5D1	N	97	98	97	80	80	80
		Mean	13.7	13.6	0.0	17.5	11.7	-5.8
		SD	23.94	25.25	20.41	29.52	21.93	22.98
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	8.9, 18.6	8.5, 18.7	-4.1, 4.1	10.9, 24.1	6.8, 16.5	-10.9, -0.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 33.3
		Mean Diff (95% CI) [a]			0.0 (-4.1, 4.1)			-5.8 (-10.9, -0.7)
		P-value [a]			1.000			0.026
		Mean Diff (95% CI) [b]			5.8 (-0.6, 12.3)			
		P-value [b]			0.076			
		Effect Size (95% CI) [c]			0.22 (0.01, 0.44)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	95	96	95	68	68	68
		Mean	12.6	11.5	-1.1	15.7	10.8	-4.9
		SD	22.38	23.61	20.31	28.49	21.89	22.50
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	8.1, 17.2	6.7, 16.2	-5.2, 3.1	8.8, 22.6	5.5, 16.1	-10.3, 0.5
		Q1, Q3	0.0, 33.3	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 33.3
		Mean Diff (95% CI) [a]			-1.1 (-5.2, 3.1)			-4.9 (-10.3, 0.5)
		P-value [a]			0.615			0.077
		Mean Diff (95% CI) [b]			3.8 (-2.8, 10.5)			
		P-value [b]			0.256			
		Effect Size (95% CI) [c]			0.15 (-0.07, 0.36)			
	C7D1	N	78	79	78	52	52	52
		Mean	12.0	11.8	0.0	17.3	13.5	-3.8
		SD	22.13	25.06	18.61	31.99	27.42	18.26
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	7.0, 17.0	6.2, 17.4	-4.2, 4.2	8.4, 26.2	5.8, 21.1	-8.9, 1.2
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 33.3
		Mean Diff (95% CI) [a]			0.0 (-4.2, 4.2)			-3.8 (-8.9, 1.2)
		P-value [a]			1.000			0.135
		Mean Diff (95% CI) [b]			3.8 (-2.7, 10.4)			
		P-value [b]			0.247			
		Effect Size (95% CI) [c]			0.15 (-0.07, 0.36)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	74	75	74	50	50	50
		Mean	13.1	14.7	1.8	18.7	14.0	-4.7
		SD	23.29	27.53	21.99	32.41	28.64	26.95
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	7.7, 18.5	8.3, 21.0	-3.3, 6.9	9.5, 27.9	5.9, 22.1	-12.3, 3.0
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 33.3
		Mean Diff (95% CI) [a]			1.8 (-3.3, 6.9)			-4.7 (-12.3, 3.0)
		P-value [a]			0.483			0.227
		Mean Diff (95% CI) [b]			6.5 (-2.3, 15.2)			
		P-value [b]			0.145			
		Effect Size (95% CI) [c]			0.25 (0.03, 0.46)			
	C9D1	N	59	60	59	42	42	42
		Mean	13.0	13.3	0.6	19.0	11.9	-7.1
		SD	23.99	27.58	22.74	32.21	21.87	25.00
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	6.7, 19.2	6.2, 20.5	-5.4, 6.5	9.0, 29.1	5.1, 18.7	-14.9, 0.6
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 66.7	-100.0, 33.3
		Mean Diff (95% CI) [a]			0.6 (-5.4, 6.5)			-7.1 (-14.9, 0.6)
		P-value [a]			0.849			0.071
		Mean Diff (95% CI) [b]			7.7 (-1.8, 17.2)			
		P-value [b]			0.110			
		Effect Size (95% CI) [c]			0.30 (0.08, 0.51)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	53	54	53	30	30	30
		Mean	12.6	12.3	0.0	21.1	16.7	-4.4
		SD	23.77	26.14	20.67	32.14	25.89	16.91
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	6.0, 19.1	5.2, 19.5	-5.7, 5.7	9.1, 33.1	7.0, 26.3	-10.8, 1.9
		Q1, Q3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			0.0 (-5.7, 5.7)			-4.4 (-10.8, 1.9)
		P-value [a]			1.000			0.161
		Mean Diff (95% CI) [b]			4.4 (-4.4, 13.3)			
		P-value [b]			0.319			
		Effect Size (95% CI) [c]			0.17 (-0.04, 0.38)			
	C11D1	N	46	46	46	23	23	23
		Mean	10.9	10.9	0.0	15.9	10.1	-5.8
		SD	21.15	23.36	22.22	28.19	21.17	21.68
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	4.6, 17.1	3.9, 17.8	-6.6, 6.6	3.7, 28.1	1.0, 19.3	-15.2, 3.6
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 66.7	-100.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (-6.6, 6.6)			-5.8 (-15.2, 3.6)
		P-value [a]			1.000			0.213
		Mean Diff (95% CI) [b]			5.8 (-5.4, 17.0)			
		P-value [b]			0.307			
		Effect Size (95% CI) [c]			0.22 (0.01, 0.44)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	40	40	40	19	19	19
		Mean	10.0	11.7	1.7	14.0	8.8	-5.3
		SD	20.25	24.52	22.58	27.92	18.73	22.94
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	3.5, 16.5	3.8, 19.5	-5.6, 8.9	0.6, 27.5	-0.3, 17.8	-16.3, 5.8
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 100.0	-33.3, 100.0	0.0, 100.0	0.0, 66.7	-100.0, 0.0
		Mean Diff (95% CI) [a]			1.7 (-5.6, 8.9)			-5.3 (-16.3, 5.8)
		P-value [a]			0.643			0.331
		Mean Diff (95% CI) [b]			6.9 (-5.7, 19.6)			
		P-value [b]			0.278			
		Effect Size (95% CI) [c]			0.27 (0.05, 0.48)			
	C13D1	N	32	32	32	15	15	15
		Mean	6.2	5.2	-1.0	11.1	6.7	-4.4
		SD	15.70	12.30	15.80	27.22	18.69	27.79
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.6, 11.9	0.8, 9.6	-6.7, 4.7	-4.0, 26.2	-3.7, 17.0	-19.8, 10.9
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 33.3	0.0, 100.0	0.0, 66.7	-100.0, 33.3
		Mean Diff (95% CI) [a]			-1.0 (-6.7, 4.7)			-4.4 (-19.8, 10.9)
		P-value [a]			0.712			0.546
		Mean Diff (95% CI) [b]			3.4 (-9.4, 16.2)			
		P-value [b]			0.595			
		Effect Size (95% CI) [c]			0.13 (-0.08, 0.34)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	8.1	8.1	0.0	13.9	8.3	-5.6
		SD	16.73	14.51	14.43	30.01	20.72	31.25
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	2.1, 14.0	2.9, 13.2	-5.1, 5.1	-5.2, 33.0	-4.8, 21.5	-25.4, 14.3
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 66.7	0.0, 33.3	-33.3, 33.3	0.0, 100.0	0.0, 66.7	-100.0, 33.3
		Mean Diff (95% CI) [a]			0.0 (-5.1, 5.1)			-5.6 (-25.4, 14.3)
		P-value [a]			1.000			0.551
		Mean Diff (95% CI) [b]			5.6 (-8.1, 19.2)			
		P-value [b]			0.417			
		Effect Size (95% CI) [c]			0.21 (0.00, 0.43)			
	C15D1	N	28	28	28	13	13	13
		Mean	7.1	8.3	1.2	12.8	10.3	-2.6
		SD	13.93	14.70	14.29	28.99	21.01	21.35
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	1.7, 12.5	2.6, 14.0	-4.4, 6.7	-4.7, 30.3	-2.4, 23.0	-15.5, 10.3
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 100.0	0.0, 66.7	-66.7, 33.3
		Mean Diff (95% CI) [a]			1.2 (-4.4, 6.7)			-2.6 (-15.5, 10.3)
		P-value [a]			0.663			0.673
		Mean Diff (95% CI) [b]			3.8 (-7.6, 15.1)			
		P-value [b]			0.509			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.36)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	6.0	8.3	2.4	6.7	6.7	0.0
		SD	13.00	14.70	12.60	14.05	14.05	0.00
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.9, 11.0	2.6, 14.0	-2.5, 7.3	-3.4, 16.7	-3.4, 16.7	0.0, 0.0
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			2.4 (-2.5, 7.3)			0.0 (0.0, 0.0)
		P-value [a]			0.326			NE
		Mean Diff (95% CI) [b]			2.4 (-5.8, 10.5)			
		P-value [b]			0.557			
		Effect Size (95% CI) [c]			0.09 (-0.12, 0.30)			
	C17D1	N	26	26	26	7	7	7
		Mean	6.4	6.4	0.0	9.5	14.3	4.8
		SD	13.40	13.40	16.33	16.27	26.23	12.60
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	1.0, 11.8	1.0, 11.8	-6.6, 6.6	-5.5, 24.6	-10.0, 38.5	-6.9, 16.4
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
		Mean Diff (95% CI) [a]			0.0 (-6.6, 6.6)			4.8 (-6.9, 16.4)
		P-value [a]			1.000			0.356
		Mean Diff (95% CI) [b]			-4.8 (-18.4, 8.9)			
		P-value [b]			0.481			
		Effect Size (95% CI) [c]			-0.18 (-0.40, 0.03)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	6.1	9.1	3.0	9.5	14.3	4.8
		SD	13.16	15.19	14.21	16.27	26.23	12.60
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.2, 11.9	2.4, 15.8	-3.3, 9.3	-5.5, 24.6	-10.0, 38.5	-6.9, 16.4
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
		Mean Diff (95% CI) [a]			3.0 (-3.3, 9.3)			4.8 (-6.9, 16.4)
		P-value [a]			0.329			0.356
		Mean Diff (95% CI) [b]			-1.7 (-14.1, 10.6)			
		P-value [b]			0.776			
		Effect Size (95% CI) [c]			-0.07 (-0.28, 0.15)			
	C19D1	N	20	20	20	6	6	6
		Mean	6.7	11.7	5.0	11.1	16.7	5.6
		SD	13.68	16.31	16.31	17.21	27.89	13.61
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.3, 13.1	4.0, 19.3	-2.6, 12.6	-7.0, 29.2	-12.6, 45.9	-8.7, 19.8
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
		Mean Diff (95% CI) [a]			5.0 (-2.6, 12.6)			5.6 (-8.7, 19.8)
		P-value [a]			0.186			0.363
		Mean Diff (95% CI) [b]			-0.6 (-15.7, 14.6)			
		P-value [b]			0.940			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.19)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	19	19	19	4	4	4
		Mean	3.5	8.8	5.3	16.7	25.0	8.3
		SD	10.51	15.08	16.72	19.25	31.91	16.67
		Median	0.0	0.0	0.0	16.7	16.7	0.0
		95% CI	-1.6, 8.6	1.5, 16.0	-2.8, 13.3	-14.0, 47.3	-25.8, 75.8	-18.2, 34.9
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 50.0	0.0, 16.7
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
		Mean Diff (95% CI) [a]			5.3 (-2.8, 13.3)			8.3 (-18.2, 34.9)
		P-value [a]			0.187			0.391
		Mean Diff (95% CI) [b]			-3.1 (-22.2, 16.0)			
		P-value [b]			0.742			
		Effect Size (95% CI) [c]			-0.12 (-0.33, 0.10)			
	C21D1	N	18	18	18	4	4	4
		Mean	3.7	7.4	3.7	16.7	25.0	8.3
		SD	10.78	14.26	15.71	19.25	31.91	16.67
		Median	0.0	0.0	0.0	16.7	16.7	0.0
		95% CI	-1.7, 9.1	0.3, 14.5	-4.1, 11.5	-14.0, 47.3	-25.8, 75.8	-18.2, 34.9
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 50.0	0.0, 16.7
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 66.7	0.0, 33.3
		Mean Diff (95% CI) [a]			3.7 (-4.1, 11.5)			8.3 (-18.2, 34.9)
		P-value [a]			0.331			0.391
		Mean Diff (95% CI) [b]			-4.6 (-22.9, 13.7)			
		P-value [b]			0.603			
		Effect Size (95% CI) [c]			-0.18 (-0.39, 0.04)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	2.2	11.1	8.9	11.1	11.1	0.0
		SD	8.61	20.57	19.79	19.25	19.25	0.00
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	-2.5, 7.0	-0.3, 22.5	-2.1, 19.8	-36.7, 58.9	-36.7, 58.9	0.0, 0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			8.9 (-2.1, 19.8)			0.0 (0.0, 0.0)
		P-value [a]			0.104			NE
		Mean Diff (95% CI) [b]			8.9 (-15.9, 33.7)			
		P-value [b]			0.459			
		Effect Size (95% CI) [c]			0.34 (0.13, 0.56)			
	C23D1	N	11	11	11	3	3	3
		Mean	3.0	6.1	3.0	11.1	11.1	0.0
		SD	10.05	13.48	17.98	19.25	19.25	0.00
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	-3.7, 9.8	-3.0, 15.1	-9.0, 15.1	-36.7, 58.9	-36.7, 58.9	0.0, 0.0
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	-33.3, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Mean Diff (95% CI) [a]			3.0 (-9.0, 15.1)			0.0 (0.0, 0.0)
		P-value [a]			0.588			NE
		Mean Diff (95% CI) [b]			3.0 (-20.3, 26.3)			
		P-value [b]			0.782			
		Effect Size (95% CI) [c]			0.12 (-0.10, 0.33)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	3.3	10.0	6.7	0.0	0.0	0.0
		SD	10.54	16.10	14.05	0.00	0.00	0.00
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	-4.2, 10.9	-1.5, 21.5	-3.4, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			6.7 (-3.4, 16.7)			0.0 (0.0, 0.0)
		P-value [a]			0.168			NE
		Mean Diff (95% CI) [b]			6.7 (-16.3, 29.7)			
		P-value [b]			0.533			
		Effect Size (95% CI) [c]			0.26 (0.04, 0.47)			
	C25D1	N	9	9	9	0	0	0
		Mean	3.7	11.1	7.4	NE	NE	NE
		SD	11.11	16.67	14.70	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	-4.8, 12.2	-1.7, 23.9	-3.9, 18.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 33.3	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			7.4 (-3.9, 18.7)			NE (NE, NE)
		P-value [a]			0.169			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	4.2	8.3	4.2	0.0	0.0	0.0
		SD	11.79	15.43	11.79	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	-5.7, 14.0	-4.6, 21.2	-5.7, 14.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			4.2 (-5.7, 14.0)			0.0 (NE, NE)
		P-value [a]			0.351			NE
		Mean Diff (95% CI) [b]			4.2 (-25.4, 33.7)			
		P-value [b]			0.749			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			
	C27D1	N	8	8	8	1	1	1
		Mean	4.2	8.3	4.2	0.0	0.0	0.0
		SD	11.79	15.43	11.79	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	-5.7, 14.0	-4.6, 21.2	-5.7, 14.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			4.2 (-5.7, 14.0)			0.0 (NE, NE)
		P-value [a]			0.351			NE
		Mean Diff (95% CI) [b]			4.2 (-25.4, 33.7)			
		P-value [b]			0.749			
		Effect Size (95% CI) [c]			0.16 (-0.05, 0.37)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	0.0	4.8	4.8	0.0	0.0	0.0
		SD	0.00	12.60	12.60	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.0, 0.0	-6.9, 16.4	-6.9, 16.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			4.8 (-6.9, 16.4)			0.0 (NE, NE)
		P-value [a]			0.356			NE
		Mean Diff (95% CI) [b]			4.8 (-28.2, 37.7)			
		P-value [b]			0.736			
		Effect Size (95% CI) [c]			0.18 (-0.03, 0.40)			
	C29D1	N	4	4	4	1	1	1
		Mean	0.0	8.3	8.3	0.0	0.0	0.0
		SD	0.00	16.67	16.67	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.0, 0.0	-18.2, 34.9	-18.2, 34.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 16.7	0.0, 16.7	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			8.3 (-18.2, 34.9)			0.0 (NE, NE)
		P-value [a]			0.391			NE
		Mean Diff (95% CI) [b]			8.3 (-51.0, 67.6)			
		P-value [b]			0.685			
		Effect Size (95% CI) [c]			0.32 (0.11, 0.54)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
	C31D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			
	C33D1	N	3	3	3	1	1	1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			0.0 (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			0.0 (0.0, 0.0)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			0.00 (-0.21, 0.21)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	0.00	0.00	0.00	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (0.0, 0.0)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	0.0	0.0	0.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	0.0	0.0	0.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	127	128	127	124	124	124
		Mean	12.6	13.8	1.3	16.1	13.7	-2.4
		SD	22.98	24.93	26.02	27.38	25.86	24.48
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	8.6, 16.6	9.4, 18.2	-3.3, 5.9	11.3, 21.0	9.1, 18.3	-6.8, 1.9
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 0.0	0.0, 33.3	0.0, 33.3	0.0, 0.0
		Min, Max	0.0, 100.0	0.0, 100.0	-66.7, 100.0	0.0, 100.0	0.0, 100.0	-100.0, 100.0
		Mean Diff (95% CI) [a]			1.3 (-3.3, 5.9)			-2.4 (-6.8, 1.9)
		P-value [a]			0.571			0.273
		Mean Diff (95% CI) [b]			3.7 (-2.6, 10.0)			
		P-value [b]			0.243			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.36)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	9.5	16.7	7.1	33.3	37.0	3.7
		SD	15.63	21.68	26.73	40.82	45.47	35.14
		Median	0.0	0.0	0.0	0.0	0.0	0.0
		95% CI	0.5, 18.5	4.1, 29.2	-8.3, 22.6	2.0, 64.7	2.1, 72.0	-23.3, 30.7
		Q1, Q3	0.0, 33.3	0.0, 33.3	0.0, 33.3	0.0, 66.7	0.0, 66.7	0.0, 0.0
		Min, Max	0.0, 33.3	0.0, 66.7	-33.3, 66.7	0.0, 100.0	0.0, 100.0	-66.7, 66.7
		Mean Diff (95% CI) [a]			7.1 (-8.3, 22.6)			3.7 (-23.3, 30.7)
		P-value [a]			0.336			0.760
		Mean Diff (95% CI) [b]			3.4 (-23.4, 30.3)			
		P-value [b]			0.792			
		Effect Size (95% CI) [c]			0.13 (-0.08, 0.35)			
Summary Score	Baseline	N	174			165		
		Mean	78.5			77.3		
		SD	15.21			14.99		
		Median	81.2			79.9		
		95% CI	76.2, 80.8			75.0, 79.6		
		Q1, Q3	70.3, 90.4			70.0, 88.0		
		Min, Max	29.7, 100.0			22.1, 100.0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C2D1	N	152	152	152	145	145	145
		Mean	79.2	76.7	-2.5	77.6	75.2	-2.4
		SD	14.96	15.87	10.87	15.43	16.81	12.52
		95% CI	76.8, 81.6	74.1, 79.2	-4.3, -0.8	75.1, 80.2	72.5, 78.0	-4.5, -0.3
		Median	82.4	81.1	-1.4	80.9	78.5	-1.2
		Q1, Q3	70.7, 90.7	65.2, 89.7	-7.3, 3.7	70.6, 89.0	67.7, 87.4	-7.0, 4.5
		Min, Max	29.8, 100.0	22.2, 100.0	-47.8, 32.4	22.1, 100.0	19.6, 100.0	-55.5, 29.4
		Mean Diff (95% CI) [a]			-2.5 (-4.3, -0.8)			-2.4 (-4.5, -0.3)
		P-value [a]			0.005			0.023
		Mean Diff (95% CI) [b]			-0.1 (-2.8, 2.5)			
		P-value [b]			0.917			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.20)			
	C3D1	N	124	124	124	102	102	102
		Mean	79.8	79.0	-0.8	77.9	77.7	-0.2
		SD	13.88	15.04	12.62	13.46	14.39	10.92
		95% CI	77.3, 82.3	76.4, 81.7	-3.0, 1.5	75.3, 80.6	74.9, 80.6	-2.3, 2.0
		Median	82.1	81.8	-0.9	79.7	79.8	0.0
		Q1, Q3	72.1, 90.2	69.3, 91.9	-6.3, 5.8	70.7, 87.0	71.3, 87.7	-7.1, 7.2
		Min, Max	29.7, 100.0	28.3, 100.0	-40.9, 38.2	38.9, 100.0	38.0, 100.0	-27.3, 28.6
		Mean Diff (95% CI) [a]			-0.8 (-3.0, 1.5)			-0.2 (-2.3, 2.0)
		P-value [a]			0.497			0.863
		Mean Diff (95% CI) [b]			-0.6 (-3.7, 2.5)			
		P-value [b]			0.713			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.17)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	112	112	112	94	94	94
		Mean	78.9	79.8	0.9	77.4	78.6	1.1
		SD	14.59	15.60	11.40	13.72	14.99	12.77
		95% CI	76.2, 81.7	76.9, 82.7	-1.2, 3.0	74.6, 80.3	75.5, 81.6	-1.5, 3.7
		Median	81.2	83.7	1.6	79.3	80.0	1.3
		Q1, Q3	71.6, 89.9	72.1, 91.5	-6.4, 7.7	69.9, 87.0	70.2, 89.2	-6.5, 8.9
		Min, Max	29.7, 100.0	23.6, 99.5	-33.8, 40.6	38.9, 100.0	30.3, 100.0	-32.0, 39.2
		Mean Diff (95% CI) [a]			0.9 (-1.2, 3.0)			1.1 (-1.5, 3.7)
		P-value [a]			0.412			0.398
		Mean Diff (95% CI) [b]			-0.2 (-3.6, 3.1)			
		P-value [b]			0.891			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.20)			
	C5D1	N	98	98	98	80	80	80
		Mean	79.4	79.5	0.1	77.5	78.1	0.6
		SD	14.33	16.33	12.39	14.07	15.05	11.37
		95% CI	76.5, 82.3	76.2, 82.8	-2.3, 2.6	74.4, 80.6	74.7, 81.4	-2.0, 3.1
		Median	81.5	84.6	0.7	81.4	79.6	0.0
		Q1, Q3	71.9, 89.6	69.7, 92.7	-5.9, 7.9	69.7, 88.5	71.8, 88.0	-7.6, 7.0
		Min, Max	29.7, 100.0	31.0, 100.0	-50.3, 40.1	38.9, 100.0	34.9, 100.0	-25.7, 34.9
		Mean Diff (95% CI) [a]			0.1 (-2.3, 2.6)			0.6 (-2.0, 3.1)
		P-value [a]			0.913			0.654
		Mean Diff (95% CI) [b]			-0.4 (-4.0, 3.1)			
		P-value [b]			0.809			
		Effect Size (95% CI) [c]			-0.03 (-0.24, 0.18)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	96	96	96	69	69	69
		Mean	80.4	82.8	2.4	77.7	77.9	0.2
		SD	13.45	14.43	10.81	13.93	16.46	12.84
		95% CI	77.7, 83.1	79.9, 85.7	0.2, 4.6	74.4, 81.1	74.0, 81.9	-2.9, 3.3
		Median	82.1	86.1	2.6	81.8	80.4	0.7
		Q1, Q3	72.4, 90.3	74.6, 94.6	-4.4, 9.2	70.7, 88.0	71.4, 89.6	-4.4, 6.8
		Min, Max	29.8, 100.0	37.6, 100.0	-34.8, 40.1	38.9, 100.0	30.0, 100.0	-31.5, 37.4
		Mean Diff (95% CI) [a]			2.4 (0.2, 4.6)			0.2 (-2.9, 3.3)
		P-value [a]			0.033			0.882
		Mean Diff (95% CI) [b]			2.2 (-1.5, 5.8)			
		P-value [b]			0.244			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.36)			
	C7D1	N	79	79	79	53	53	53
		Mean	79.5	82.5	3.0	77.9	81.4	3.5
		SD	14.84	13.97	10.05	14.78	14.31	11.54
		95% CI	76.2, 82.8	79.4, 85.6	0.7, 5.2	73.8, 81.9	77.4, 85.3	0.3, 6.7
		Median	82.1	84.4	3.2	81.8	83.9	1.4
		Q1, Q3	71.7, 90.6	77.3, 93.1	-4.3, 8.3	71.8, 89.0	74.0, 90.6	-2.4, 9.1
		Min, Max	29.7, 100.0	33.2, 100.0	-20.0, 42.4	38.9, 100.0	43.1, 100.0	-30.9, 37.0
		Mean Diff (95% CI) [a]			3.0 (0.7, 5.2)			3.5 (0.3, 6.7)
		P-value [a]			0.010			0.032
		Mean Diff (95% CI) [b]			-0.5 (-4.2, 3.2)			
		P-value [b]			0.793			
		Effect Size (95% CI) [c]			-0.03 (-0.25, 0.18)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	76	76	76	50	50	50
		Mean	79.3	81.9	2.5	77.4	81.0	3.6
		SD	14.73	16.62	11.81	15.11	15.65	12.49
		95% CI	76.0, 82.7	78.1, 85.7	-0.2, 5.2	73.1, 81.7	76.5, 85.4	0.0, 7.1
		Median	81.5	86.8	3.3	80.0	83.8	2.4
		Q1, Q3	72.3, 89.9	75.0, 93.4	-2.1, 8.5	70.7, 89.0	77.4, 90.5	-1.8, 7.7
		Min, Max	29.7, 100.0	28.8, 100.0	-40.6, 27.1	38.9, 100.0	25.0, 100.0	-34.7, 32.0
		Mean Diff (95% CI) [a]			2.5 (-0.2, 5.2)			3.6 (0.0, 7.1)
		P-value [a]			0.067			0.050
		Mean Diff (95% CI) [b]			-1.0 (-5.4, 3.3)			
		P-value [b]			0.640			
		Effect Size (95% CI) [c]			-0.07 (-0.28, 0.14)			
	C9D1	N	60	60	60	42	42	42
		Mean	80.2	81.8	1.6	76.9	80.6	3.7
		SD	13.10	15.19	10.94	15.56	14.52	11.06
		95% CI	76.8, 83.6	77.9, 85.7	-1.2, 4.5	72.0, 81.7	76.1, 85.2	0.3, 7.2
		Median	80.6	87.0	2.3	80.0	82.9	1.8
		Q1, Q3	71.6, 90.3	73.3, 93.9	-5.7, 7.1	67.4, 89.0	75.0, 91.6	-2.1, 8.4
		Min, Max	43.2, 100.0	43.7, 100.0	-36.0, 27.1	38.9, 100.0	36.9, 100.0	-16.2, 33.5
		Mean Diff (95% CI) [a]			1.6 (-1.2, 4.5)			3.7 (0.3, 7.2)
		P-value [a]			0.250			0.034
		Mean Diff (95% CI) [b]			-2.1 (-6.5, 2.3)			
		P-value [b]			0.343			
		Effect Size (95% CI) [c]			-0.14 (-0.35, 0.07)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	54	54	54	30	30	30
		Mean	80.0	82.2	2.2	75.1	77.5	2.4
		SD	13.28	13.62	10.10	15.77	16.00	10.63
		95% CI	76.4, 83.6	78.4, 85.9	-0.6, 4.9	69.2, 81.0	71.5, 83.5	-1.6, 6.4
		Median	80.6	85.5	0.9	78.3	83.9	2.0
		Q1, Q3	71.4, 90.6	75.8, 91.5	-4.4, 8.8	65.4, 87.3	69.0, 88.8	-3.7, 4.6
		Min, Max	43.2, 100.0	47.3, 100.0	-18.5, 27.1	38.9, 96.7	41.5, 96.2	-20.7, 25.8
		Mean Diff (95% CI) [a]			2.2 (-0.6, 4.9)			2.4 (-1.6, 6.4)
		P-value [a]			0.120			0.223
		Mean Diff (95% CI) [b]			-0.2 (-4.9, 4.4)			
		P-value [b]			0.919			
		Effect Size (95% CI) [c]			-0.02 (-0.23, 0.20)			
	C11D1	N	46	46	46	23	23	23
		Mean	79.3	80.1	0.8	79.3	82.5	3.2
		SD	13.52	15.64	13.92	13.34	9.21	12.87
		95% CI	75.3, 83.4	75.5, 84.8	-3.3, 4.9	73.5, 85.1	78.5, 86.5	-2.4, 8.8
		Median	80.6	83.9	3.3	81.8	82.1	2.4
		Q1, Q3	71.4, 89.1	71.7, 91.9	-6.3, 9.1	70.7, 90.6	78.0, 90.2	-6.5, 7.2
		Min, Max	43.2, 100.0	41.3, 100.0	-45.4, 27.1	50.0, 96.7	57.2, 97.4	-15.5, 32.1
		Mean Diff (95% CI) [a]			0.8 (-3.3, 4.9)			3.2 (-2.4, 8.8)
		P-value [a]			0.699			0.246
		Mean Diff (95% CI) [b]			-2.4 (-9.3, 4.5)			
		P-value [b]			0.492			
		Effect Size (95% CI) [c]			-0.16 (-0.37, 0.05)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	41	41	41	19	19	19
		Mean	80.6	82.1	1.5	80.0	84.5	4.5
		SD	13.61	16.05	11.13	10.67	12.15	13.06
		Median	82.1	86.8	0.6	81.8	87.9	3.9
		95% CI	76.3, 84.9	77.0, 87.1	-2.0, 5.0	74.9, 85.2	78.7, 90.4	-1.8, 10.8
		Q1, Q3	72.2, 92.1	75.8, 93.8	-4.5, 5.8	70.7, 90.4	80.6, 91.3	-5.4, 10.1
		Min, Max	43.2, 100.0	41.2, 100.0	-27.9, 24.1	63.2, 96.7	44.5, 97.4	-20.9, 30.8
		Mean Diff (95% CI) [a]			1.5 (-2.0, 5.0)			4.5 (-1.8, 10.8)
		P-value [a]			0.395			0.149
		Mean Diff (95% CI) [b]			-3.0 (-9.6, 3.5)			
		P-value [b]			0.358			
		Effect Size (95% CI) [c]			-0.20 (-0.41, 0.01)			
	C13D1	N	33	33	33	15	15	15
		Mean	81.3	80.8	-0.5	78.2	84.0	5.8
		SD	13.10	15.90	14.51	13.66	9.85	13.96
		Median	83.3	82.6	-0.6	79.9	86.3	5.1
		95% CI	76.7, 86.0	75.2, 86.5	-5.6, 4.7	70.7, 85.8	78.6, 89.5	-1.9, 13.5
		Q1, Q3	72.4, 92.3	73.3, 90.7	-8.0, 7.4	65.3, 90.4	73.6, 89.4	-7.3, 17.0
		Min, Max	46.3, 100.0	32.7, 100.0	-53.8, 26.5	50.0, 96.7	66.1, 100.0	-16.8, 29.4
		Mean Diff (95% CI) [a]			-0.5 (-5.6, 4.7)			5.8 (-1.9, 13.5)
		P-value [a]			0.851			0.130
		Mean Diff (95% CI) [b]			-6.3 (-15.3, 2.7)			
		P-value [b]			0.167			
		Effect Size (95% CI) [c]			-0.41 (-0.63, -0.20)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	33	33	33	12	12	12
		Mean	81.4	82.5	1.1	77.5	83.1	5.5
		SD	13.19	13.19	10.80	13.82	14.24	14.59
		Median	83.3	82.6	0.6	77.9	85.4	6.5
		95% CI	76.7, 86.0	77.8, 87.1	-2.7, 4.9	68.7, 86.3	74.0, 92.1	-3.7, 14.8
		Q1, Q3	72.4, 92.3	73.1, 92.6	-4.9, 7.7	68.0, 88.9	72.9, 96.1	-5.7, 12.0
		Min, Max	46.3, 100.0	52.3, 100.0	-19.5, 25.9	50.0, 96.7	58.3, 99.5	-14.1, 34.2
		Mean Diff (95% CI) [a]			1.1 (-2.7, 4.9)			5.5 (-3.7, 14.8)
		P-value [a]			0.562			0.215
		Mean Diff (95% CI) [b]			-4.4 (-12.5, 3.6)			
		P-value [b]			0.275			
		Effect Size (95% CI) [c]			-0.29 (-0.51, -0.08)			
	C15D1	N	28	28	28	13	13	13
		Mean	80.3	80.0	-0.3	76.6	78.3	1.7
		SD	13.42	14.81	12.85	13.67	11.70	12.27
		Median	82.2	83.0	2.7	76.0	80.6	3.6
		95% CI	75.1, 85.5	74.3, 85.8	-5.3, 4.7	68.3, 84.8	71.2, 85.4	-5.7, 9.1
		Q1, Q3	71.9, 92.2	71.0, 90.3	-8.8, 7.9	65.3, 87.3	72.3, 86.8	-9.4, 10.6
		Min, Max	46.3, 100.0	39.5, 100.0	-27.7, 25.9	50.0, 96.7	59.1, 93.5	-18.8, 22.9
		Mean Diff (95% CI) [a]			-0.3 (-5.3, 4.7)			1.7 (-5.7, 9.1)
		P-value [a]			0.907			0.622
		Mean Diff (95% CI) [b]			-2.0 (-10.6, 6.6)			
		P-value [b]			0.640			
		Effect Size (95% CI) [c]			-0.13 (-0.35, 0.08)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

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[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	28	28	28	10	10	10
		Mean	81.2	81.6	0.4	75.2	79.0	3.7
		SD	12.95	13.25	10.60	14.11	11.97	11.29
		Median	83.9	82.6	1.0	74.2	83.2	4.0
		95% CI	76.1, 86.2	76.4, 86.7	-3.7, 4.5	65.1, 85.3	70.4, 87.5	-4.3, 11.8
		Q1, Q3	73.4, 92.2	70.5, 92.6	-6.5, 5.0	65.1, 87.3	66.3, 86.5	-4.5, 9.7
		Min, Max	46.3, 96.8	55.4, 100.0	-19.8, 27.1	50.0, 96.7	58.6, 96.1	-13.5, 24.5
		Mean Diff (95% CI) [a]			0.4 (-3.7, 4.5)			3.7 (-4.3, 11.8)
		P-value [a]			0.846			0.321
		Mean Diff (95% CI) [b]			-3.4 (-11.4, 4.7)			
		P-value [b]			0.404			
		Effect Size (95% CI) [c]			-0.22 (-0.43, -0.01)			
	C17D1	N	26	26	26	7	7	7
		Mean	80.8	82.3	1.5	71.4	80.2	8.8
		SD	13.34	14.83	11.68	12.06	13.70	10.41
		Median	83.9	85.9	3.1	72.4	83.3	10.1
		95% CI	75.4, 86.2	76.3, 88.3	-3.2, 6.3	60.2, 82.5	67.5, 92.9	-0.8, 18.5
		Q1, Q3	72.2, 92.1	72.6, 95.3	-3.8, 7.7	63.2, 79.9	66.3, 90.9	-4.2, 14.8
		Min, Max	46.3, 100.0	50.3, 100.0	-24.2, 27.1	50.0, 87.3	59.5, 97.4	-4.4, 25.0
		Mean Diff (95% CI) [a]			1.5 (-3.2, 6.3)			8.8 (-0.8, 18.5)
		P-value [a]			0.507			0.066
		Mean Diff (95% CI) [b]			-7.3 (-17.2, 2.7)			
		P-value [b]			0.145			
		Effect Size (95% CI) [c]			-0.48 (-0.70, -0.27)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	22	22	22	7	7	7
		Mean	79.4	81.2	1.8	76.1	81.9	5.8
		SD	13.76	16.57	12.75	14.66	12.75	11.68
		Median	81.6	84.0	2.9	76.0	84.6	6.4
		95% CI	73.3, 85.5	73.9, 88.6	-3.8, 7.5	62.6, 89.7	70.1, 93.7	-5.0, 16.6
		Q1, Q3	71.5, 92.1	69.4, 97.4	-3.1, 9.7	70.7, 87.3	69.6, 93.7	-5.7, 12.3
		Min, Max	46.3, 96.8	45.1, 100.0	-29.7, 26.5	50.0, 96.7	65.0, 100.0	-10.3, 24.9
		Mean Diff (95% CI) [a]			1.8 (-3.8, 7.5)			5.8 (-5.0, 16.6)
		P-value [a]			0.514			0.237
		Mean Diff (95% CI) [b]			-4.0 (-15.1, 7.2)			
		P-value [b]			0.469			
		Effect Size (95% CI) [c]			-0.26 (-0.48, -0.05)			
	C19D1	N	20	20	20	6	6	6
		Mean	79.5	81.5	2.0	77.0	76.5	-0.5
		SD	14.33	14.88	11.41	15.84	11.13	12.74
		Median	81.6	84.3	1.6	77.9	78.9	0.5
		95% CI	72.8, 86.2	74.6, 88.5	-3.3, 7.4	60.4, 93.7	64.8, 88.2	-13.9, 12.8
		Q1, Q3	71.4, 92.2	72.0, 91.6	-3.9, 8.2	72.4, 87.3	63.9, 83.3	-12.8, 11.0
		Min, Max	46.3, 96.8	49.4, 100.0	-22.0, 26.3	50.0, 96.7	63.5, 90.5	-15.9, 13.5
		Mean Diff (95% CI) [a]			2.0 (-3.3, 7.4)			-0.5 (-13.9, 12.8)
		P-value [a]			0.435			0.923
		Mean Diff (95% CI) [b]			2.6 (-8.7, 13.8)			
		P-value [b]			0.642			
		Effect Size (95% CI) [c]			0.17 (-0.04, 0.38)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	20	20	20	4	4	4
		Mean	81.9	80.2	-1.7	72.4	79.7	7.3
		SD	15.27	15.71	11.49	16.12	11.51	9.35
		Median	86.3	83.0	-1.2	76.1	80.1	9.0
		95% CI	74.8, 89.1	72.8, 87.5	-7.1, 3.6	46.7, 98.0	61.4, 98.0	-7.5, 22.2
		Q1, Q3	73.1, 95.1	72.4, 89.2	-5.7, 4.0	61.2, 83.6	70.6, 88.8	0.2, 14.5
		Min, Max	46.3, 100.0	40.4, 100.0	-36.0, 23.5	50.0, 87.3	66.2, 92.5	-4.9, 16.2
		Mean Diff (95% CI) [a]			-1.7 (-7.1, 3.6)			7.3 (-7.5, 22.2)
		P-value [a]			0.505			0.215
		Mean Diff (95% CI) [b]			-9.1 (-21.8, 3.7)			
		P-value [b]			0.153			
		Effect Size (95% CI) [c]			-0.60 (-0.82, -0.38)			
	C21D1	N	18	18	18	4	4	4
		Mean	80.1	82.7	2.6	72.4	77.9	5.6
		SD	14.99	13.12	9.99	16.12	11.83	7.91
		Median	84.7	83.1	2.2	76.1	77.8	6.7
		95% CI	72.6, 87.6	76.2, 89.2	-2.4, 7.6	46.7, 98.0	59.1, 96.8	-7.0, 18.1
		Q1, Q3	71.5, 92.3	76.6, 89.7	-4.5, 7.7	61.2, 83.6	69.4, 86.5	0.0, 11.1
		Min, Max	46.3, 96.8	48.9, 100.0	-16.5, 23.5	50.0, 87.3	63.8, 92.2	-5.0, 13.8
		Mean Diff (95% CI) [a]			2.6 (-2.4, 7.6)			5.6 (-7.0, 18.1)
		P-value [a]			0.286			0.255
		Mean Diff (95% CI) [b]			-3.0 (-14.2, 8.2)			
		P-value [b]			0.587			
		Effect Size (95% CI) [c]			-0.20 (-0.41, 0.02)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	15	15	15	3	3	3
		Mean	81.8	80.3	-1.4	69.9	84.4	14.5
		SD	14.69	16.15	12.09	18.78	14.62	5.87
		Median	86.2	83.8	2.6	72.4	82.1	12.7
		95% CI	73.7, 89.9	71.4, 89.3	-8.1, 5.3	23.2, 116.5	48.0, 120.7	-0.1, 29.1
		Q1, Q3	74.6, 95.4	70.1, 91.8	-5.0, 3.3	50.0, 87.3	71.0, 100.0	9.7, 21.0
		Min, Max	46.3, 96.8	48.9, 100.0	-36.1, 12.9	50.0, 87.3	71.0, 100.0	9.7, 21.0
		Mean Diff (95% CI) [a]			-1.4 (-8.1, 5.3)			14.5 (-0.1, 29.1)
		P-value [a]			0.651			0.051
		Mean Diff (95% CI) [b]			-15.9 (-31.3, -0.5)			
		P-value [b]			0.044			
		Effect Size (95% CI) [c]			-1.05 (-1.28, -0.82)			
	C23D1	N	11	11	11	3	3	3
		Mean	80.6	80.8	0.2	69.9	81.5	11.6
		SD	16.29	15.87	8.71	18.78	16.27	2.89
		Median	86.2	87.0	-0.6	72.4	82.1	10.1
		95% CI	69.7, 91.6	70.2, 91.5	-5.6, 6.1	23.2, 116.5	41.1, 121.9	4.4, 18.8
		Q1, Q3	71.5, 94.9	70.9, 93.4	-4.6, 7.3	50.0, 87.3	64.9, 97.4	9.7, 14.9
		Min, Max	46.3, 96.8	45.8, 98.7	-19.3, 13.5	50.0, 87.3	64.9, 97.4	9.7, 14.9
		Mean Diff (95% CI) [a]			0.2 (-5.6, 6.1)			11.6 (4.4, 18.8)
		P-value [a]			0.938			0.020
		Mean Diff (95% CI) [b]			-11.4 (-22.8, 0.0)			
		P-value [b]			0.051			
		Effect Size (95% CI) [c]			-0.75 (-0.97, -0.53)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	10	10	10	2	2	2
		Mean	82.8	80.5	-2.4	68.7	79.6	10.9
		SD	15.38	19.14	6.40	26.38	21.79	4.59
		Median	86.3	85.7	-1.2	68.7	79.6	10.9
		95% CI	71.8, 93.8	66.8, 94.2	-6.9, 2.2	-168.4, 305.7	-116.2, 275.3	-30.3, 52.2
		Q1, Q3	75.1, 94.9	68.7, 95.7	-6.7, 0.0	50.0, 87.3	64.2, 95.0	7.7, 14.2
		Min, Max	46.3, 96.8	36.3, 97.6	-10.3, 11.2	50.0, 87.3	64.2, 95.0	7.7, 14.2
		Mean Diff (95% CI) [a]			-2.4 (-6.9, 2.2)			10.9 (-30.3, 52.2)
		P-value [a]			0.275			0.184
		Mean Diff (95% CI) [b]			-13.3 (-24.1, -2.5)			
		P-value [b]			0.020			
		Effect Size (95% CI) [c]			-0.88 (-1.10, -0.66)			
	C25D1	N	9	9	9	0	0	0
		Mean	81.3	78.4	-2.9	NE	NE	NE
		SD	15.46	17.60	8.33	NE	NE	NE
		Median	86.2	81.2	-2.6	NE	NE	NE
		95% CI	69.4, 93.2	64.8, 91.9	-9.3, 3.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	75.1, 92.1	75.6, 87.0	-6.4, 0.5	NE, NE	NE, NE	NE, NE
		Min, Max	46.3, 95.4	39.9, 100.0	-18.1, 13.5	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-2.9 (-9.3, 3.5)			NE (NE, NE)
		P-value [a]			0.326			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	8	8	8	1	1	1
		Mean	88.8	82.8	-6.0	87.3	98.7	11.4
		SD	7.42	16.77	16.33	NE	NE	NE
		Median	89.3	86.6	-0.4	87.3	98.7	11.4
		95% CI	82.6, 95.0	68.7, 96.8	-19.7, 7.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	84.7, 95.1	73.7, 95.0	-9.5, 2.5	87.3, 87.3	98.7, 98.7	11.4, 11.4
		Min, Max	75.1, 96.8	52.6, 98.7	-42.8, 9.6	87.3, 87.3	98.7, 98.7	11.4, 11.4
		Mean Diff (95% CI) [a]			-6.0 (-19.7, 7.6)			11.4 (NE, NE)
		P-value [a]			0.331			NE
		Mean Diff (95% CI) [b]			-17.4 (-58.4, 23.5)			
		P-value [b]			0.348			
		Effect Size (95% CI) [c]			-1.15 (-1.38, -0.92)			
	C27D1	N	8	8	8	1	1	1
		Mean	88.8	87.9	-0.9	87.3	96.8	9.5
		SD	7.42	9.68	9.48	NE	NE	NE
		Median	89.3	90.3	0.3	87.3	96.8	9.5
		95% CI	82.6, 95.0	79.8, 96.0	-8.8, 7.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	84.7, 95.1	79.9, 94.8	-2.4, 2.3	87.3, 87.3	96.8, 96.8	9.5, 9.5
		Min, Max	75.1, 96.8	73.6, 100.0	-20.7, 13.5	87.3, 87.3	96.8, 96.8	9.5, 9.5
		Mean Diff (95% CI) [a]			-0.9 (-8.8, 7.1)			9.5 (NE, NE)
		P-value [a]			0.806			NE
		Mean Diff (95% CI) [b]			-10.3 (-34.1, 13.4)			
		P-value [b]			0.338			
		Effect Size (95% CI) [c]			-0.68 (-0.90, -0.46)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	7	7	7	1	1	1
		Mean	89.2	88.1	-1.1	87.3	96.9	9.6
		SD	7.93	8.45	8.06	NE	NE	NE
		Median	92.1	89.6	-1.5	87.3	96.9	9.6
		95% CI	81.8, 96.5	80.3, 95.9	-8.5, 6.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 95.4	80.0, 97.4	-2.6, 2.3	87.3, 87.3	96.9, 96.9	9.6, 9.6
		Min, Max	75.1, 96.8	77.4, 98.2	-15.5, 11.7	87.3, 87.3	96.9, 96.9	9.6, 9.6
		Mean Diff (95% CI) [a]			-1.1 (-8.5, 6.4)			9.6 (NE, NE)
		P-value [a]			0.735			NE
		Mean Diff (95% CI) [b]			-10.7 (-31.8, 10.4)			
		P-value [b]			0.261			
		Effect Size (95% CI) [c]			-0.71 (-0.93, -0.49)			
	C29D1	N	4	4	4	1	1	1
		Mean	85.1	81.5	-3.6	87.3	70.9	-16.5
		SD	8.39	13.17	16.79	NE	NE	NE
		Median	84.9	79.9	0.7	87.3	70.9	-16.5
		95% CI	71.7, 98.4	60.5, 102.4	-30.3, 23.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	79.2, 91.0	71.4, 91.6	-13.9, 6.7	87.3, 87.3	70.9, 70.9	-16.5, -16.5
		Min, Max	75.1, 95.4	67.9, 98.2	-27.5, 11.7	87.3, 87.3	70.9, 70.9	-16.5, -16.5
		Mean Diff (95% CI) [a]			-3.6 (-30.3, 23.1)			-16.5 (NE, NE)
		P-value [a]			0.697			NE
		Mean Diff (95% CI) [b]			12.9 (-46.9, 72.6)			
		P-value [b]			0.543			
		Effect Size (95% CI) [c]			0.85 (0.63, 1.07)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	90.5	91.0	0.5	87.3	60.9	-26.4
		SD	6.62	9.17	11.46	NE	NE	NE
		Median	91.0	91.5	1.4	87.3	60.9	-26.4
		95% CI	80.0, 101.0	76.4, 105.6	-17.8, 18.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	84.9, 96.1	83.3, 98.7	-6.9, 7.8	87.3, 87.3	60.9, 60.9	-26.4, -26.4
		Min, Max	83.3, 96.8	81.0, 100.0	-14.4, 13.5	87.3, 87.3	60.9, 60.9	-26.4, -26.4
		Mean Diff (95% CI) [a]			0.5 (-17.8, 18.7)			-26.4 (NE, NE)
		P-value [a]			0.938			NE
		Mean Diff (95% CI) [b]			26.8 (-13.9, 67.6)			
		P-value [b]			0.127			
		Effect Size (95% CI) [c]			1.77 (1.52, 2.02)			
	C31D1	N	2	2	2	1	1	1
		Mean	84.9	89.5	4.6	87.3	81.8	-5.5
		SD	2.24	12.36	10.12	NE	NE	NE
		Median	84.9	89.5	4.6	87.3	81.8	-5.5
		95% CI	64.8, 105.0	-21.6, 200.5	-86.4, 95.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 86.5	80.7, 98.2	-2.6, 11.7	87.3, 87.3	81.8, 81.8	-5.5, -5.5
		Min, Max	83.3, 86.5	80.7, 98.2	-2.6, 11.7	87.3, 87.3	81.8, 81.8	-5.5, -5.5
		Mean Diff (95% CI) [a]			4.6 (-86.4, 95.5)			-5.5 (NE, NE)
		P-value [a]			0.639			NE
		Mean Diff (95% CI) [b]			10.1 (-147.5, 167.6)			
		P-value [b]			0.566			
		Effect Size (95% CI) [c]			0.66 (0.45, 0.88)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	84.9	91.6	6.7	87.3	82.9	-4.4
		SD	2.24	11.09	8.85	NE	NE	NE
		Median	84.9	91.6	6.7	87.3	82.9	-4.4
		95% CI	64.8, 105.0	-8.0, 191.3	-72.8, 86.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 86.5	83.8, 99.5	0.5, 13.0	87.3, 87.3	82.9, 82.9	-4.4, -4.4
		Min, Max	83.3, 86.5	83.8, 99.5	0.5, 13.0	87.3, 87.3	82.9, 82.9	-4.4, -4.4
		Mean Diff (95% CI) [a]			6.7 (-72.8, 86.3)			-4.4 (NE, NE)
		P-value [a]			0.477			NE
		Mean Diff (95% CI) [b]			11.1 (-126.7, 148.9)			
		P-value [b]			0.493			
		Effect Size (95% CI) [c]			0.73 (0.51, 0.95)			
	C33D1	N	3	3	3	1	1	1
		Mean	88.9	91.3	2.4	87.3	81.7	-5.6
		SD	7.04	8.33	5.82	NE	NE	NE
		Median	86.5	95.6	-0.2	87.3	81.7	-5.6
		95% CI	71.4, 106.4	70.6, 112.0	-12.1, 16.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 96.8	81.7, 96.6	-1.7, 9.1	87.3, 87.3	81.7, 81.7	-5.6, -5.6
		Min, Max	83.3, 96.8	81.7, 96.6	-1.7, 9.1	87.3, 87.3	81.7, 81.7	-5.6, -5.6
		Mean Diff (95% CI) [a]			2.4 (-12.1, 16.8)			-5.6 (NE, NE)
		P-value [a]			0.550			NE
		Mean Diff (95% CI) [b]			8.0 (-20.9, 36.9)			
		P-value [b]			0.354			
		Effect Size (95% CI) [c]			0.53 (0.31, 0.75)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	3	3	3	0	0	0
		Mean	88.9	88.5	-0.4	NE	NE	NE
		SD	7.04	16.57	13.11	NE	NE	NE
		Median	86.5	97.4	0.6	NE	NE	NE
		95% CI	71.4, 106.4	47.4, 129.7	-32.9, 32.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 96.8	69.4, 98.7	-13.9, 12.2	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 96.8	69.4, 98.7	-13.9, 12.2	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-0.4 (-32.9, 32.2)			NE (NE, NE)
		P-value [a]			0.967			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	84.9	85.6	0.7	NE	NE	NE
		SD	2.24	15.96	13.72	NE	NE	NE
		Median	84.9	85.6	0.7	NE	NE	NE
		95% CI	64.8, 105.0	-57.7, 229.0	-122.5, 124.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 86.5	74.4, 96.9	-9.0, 10.4	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 86.5	74.4, 96.9	-9.0, 10.4	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			0.7 (-122.5, 124.0)			NE (NE, NE)
		P-value [a]			0.952			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	88.9	90.6	1.7	NE	NE	NE
		SD	7.04	13.66	10.77	NE	NE	NE
		Median	86.5	97.4	0.6	NE	NE	NE
		95% CI	71.4, 106.4	56.7, 124.5	-25.0, 28.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 96.8	74.9, 99.5	-8.5, 13.0	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 96.8	74.9, 99.5	-8.5, 13.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			1.7 (-25.0, 28.5)			NE (NE, NE)
		P-value [a]			0.808			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	88.9	90.8	1.9	NE	NE	NE
		SD	7.04	13.36	10.53	NE	NE	NE
		Median	86.5	97.4	0.6	NE	NE	NE
		95% CI	71.4, 106.4	57.6, 124.0	-24.3, 28.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	83.3, 96.8	75.4, 99.5	-7.9, 13.0	NE, NE	NE, NE	NE, NE
		Min, Max	83.3, 96.8	75.4, 99.5	-7.9, 13.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			1.9 (-24.3, 28.0)			NE (NE, NE)
		P-value [a]			0.785			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	91.6	97.2	5.5	NE	NE	NE
		SD	7.28	0.36	6.92	NE	NE	NE
		Median	91.6	97.2	5.5	NE	NE	NE
		95% CI	26.2, 157.1	93.9, 100.4	-56.6, 67.7	NE, NE	NE, NE	NE, NE
		Q1, Q3	86.5, 96.8	96.9, 97.4	0.6, 10.4	NE, NE	NE, NE	NE, NE
		Min, Max	86.5, 96.8	96.9, 97.4	0.6, 10.4	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			5.5 (-56.6, 67.7)			NE (NE, NE)
		P-value [a]			0.461			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	91.6	100.0	8.4	NE	NE	NE
		SD	7.28	0.00	7.28	NE	NE	NE
		Median	91.6	100.0	8.4	NE	NE	NE
		95% CI	26.2, 157.1	100.0, 100.0	-57.1, 73.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	86.5, 96.8	100.0, 100.0	3.2, 13.5	NE, NE	NE, NE	NE, NE
		Min, Max	86.5, 96.8	100.0, 100.0	3.2, 13.5	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.4 (-57.1, 73.8)			NE (NE, NE)
		P-value [a]			0.352			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	91.6	97.8	6.2	NE	NE	NE
		SD	7.28	3.08	4.20	NE	NE	NE
		Median	91.6	97.8	6.2	NE	NE	NE
		95% CI	26.2, 157.1	70.1, 125.5	-31.6, 43.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	86.5, 96.8	95.6, 100.0	3.2, 9.1	NE, NE	NE, NE	NE, NE
		Min, Max	86.5, 96.8	95.6, 100.0	3.2, 9.1	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			6.2 (-31.6, 43.9)			NE (NE, NE)
		P-value [a]			0.285			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	91.6	96.3	4.7	NE	NE	NE
		SD	7.28	5.20	2.09	NE	NE	NE
		Median	91.6	96.3	4.7	NE	NE	NE
		95% CI	26.2, 157.1	49.6, 143.0	-14.1, 23.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	86.5, 96.8	92.6, 100.0	3.2, 6.2	NE, NE	NE, NE	NE, NE
		Min, Max	86.5, 96.8	92.6, 100.0	3.2, 6.2	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			4.7 (-14.1, 23.4)			NE (NE, NE)
		P-value [a]			0.194			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	86.5	94.2	7.7	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	86.5	94.2	7.7	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	86.5, 86.5	94.2, 94.2	7.7, 7.7	NE, NE	NE, NE	NE, NE
		Min, Max	86.5, 86.5	94.2, 94.2	7.7, 7.7	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			7.7 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	86.5	95.1	8.6	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	86.5	95.1	8.6	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	86.5, 86.5	95.1, 95.1	8.6, 8.6	NE, NE	NE, NE	NE, NE
		Min, Max	86.5, 86.5	95.1, 95.1	8.6, 8.6	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.6 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.1
EORTC QLQ-C30 Scores and Change from Baseline by Visit
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=174)			TPC (N=165)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	131	131	131	126	126	126
		Mean	78.5	73.9	-4.6	78.2	74.2	-4.0
		SD	15.88	21.31	16.09	14.95	18.28	14.69
		Median	81.1	78.9	-1.3	83.0	77.1	-2.6
		95% CI	75.7, 81.2	70.2, 77.6	-7.4, -1.8	75.6, 80.9	71.0, 77.4	-6.6, -1.4
		Q1, Q3	71.2, 90.8	61.2, 90.3	-13.0, 5.8	70.3, 89.0	62.8, 87.8	-12.5, 5.1
		Min, Max	29.7, 100.0	7.7, 100.0	-52.9, 41.4	22.1, 100.0	16.9, 100.0	-58.3, 36.3
		Mean Diff (95% CI) [a]			-4.6 (-7.4, -1.8)			-4.0 (-6.6, -1.4)
		P-value [a]			0.001			0.003
		Mean Diff (95% CI) [b]			-0.6 (-4.3, 3.2)			
		P-value [b]			0.772			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.18)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	85.3	79.8	-5.5	78.9	62.5	-16.4
		SD	9.08	13.76	8.97	13.86	27.41	25.08
		Median	86.0	79.1	-3.5	83.5	70.3	-9.2
		95% CI	80.1, 90.6	71.9, 87.7	-10.7, -0.4	68.2, 89.5	41.4, 83.5	-35.7, 2.9
		Q1, Q3	78.7, 93.2	70.3, 94.0	-14.4, 1.9	73.5, 85.7	57.3, 78.9	-21.8, -3.4
		Min, Max	70.1, 97.8	58.1, 97.7	-20.6, 6.9	52.2, 100.0	8.2, 96.6	-75.3, 10.2
		Mean Diff (95% CI) [a]			-5.5 (-10.7, -0.4)			-16.4 (-35.7, 2.9)
		P-value [a]			0.038			0.085
		Mean Diff (95% CI) [b]			10.9 (-4.3, 26.0)			
		P-value [b]			0.150			
		Effect Size (95% CI) [c]			0.72 (0.50, 0.94)			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. CI = Confidence Interval; Diff = Difference; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; NE = Not Estimable; QoL = quality of life; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.

[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.

[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.

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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
EQ-5D VAS	Baseline	N	171			163		
		Mean	69.4			68.5		
		SD	19.34			20.29		
		Median	75.0			70.0		
		95% CI	66.5, 72.4			65.4, 71.6		
		Q1, Q3	60.0, 80.0			50.0, 85.0		
		Min, Max	6.0, 100.0			7.0, 100.0		
	C2D1	N	147	151	147	143	143	143
		Mean	70.5	69.9	-0.6	70.0	68.0	-2.0
		SD	18.98	19.84	16.08	19.42	19.43	14.15
		Median	75.0	70.0	0.0	70.0	70.0	0.0
		95% CI	67.4, 73.6	66.7, 73.1	-3.2, 2.0	66.8, 73.2	64.7, 71.2	-4.4, 0.3
		Q1, Q3	60.0, 80.0	60.0, 85.0	-5.0, 5.0	51.0, 85.0	50.0, 85.0	-10.0, 5.0
		Min, Max	6.0, 100.0	7.0, 100.0	-63.0, 50.0	7.0, 100.0	6.0, 100.0	-59.0, 63.0
		Mean Diff (95% CI) [a]			-0.6 (-3.2, 2.0)			-2.0 (-4.4, 0.3)
		P-value [a]			0.652			0.091
		Mean Diff (95% CI) [b]			1.4 (-2.1, 4.9)			
		P-value [b]			0.427			
		Effect Size (95% CI) [c]			0.07 (-0.14, 0.29)			
	C3D1	N	121	124	121	103	103	103
		Mean	70.6	72.3	1.5	70.7	72.4	1.7
		SD	18.58	17.92	14.33	18.17	16.09	12.02
		Median	75.0	75.0	0.0	70.0	75.0	0.0
		95% CI	67.3, 74.0	69.1, 75.5	-1.0, 4.1	67.2, 74.3	69.2, 75.5	-0.7, 4.0
		Q1, Q3	60.0, 85.0	60.0, 85.0	-5.0, 10.0	51.0, 85.0	60.0, 85.0	-5.0, 10.0
		Min, Max	10.0, 100.0	30.0, 100.0	-35.0, 60.0	30.0, 100.0	40.0, 100.0	-30.0, 45.0
		Mean Diff (95% CI) [a]			1.5 (-1.0, 4.1)			1.7 (-0.7, 4.0)
		P-value [a]			0.240			0.162
		Mean Diff (95% CI) [b]			-0.1 (-3.7, 3.4)			
		P-value [b]			0.941			
		Effect Size (95% CI) [c]			-0.01 (-0.22, 0.21)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C4D1	N	108	110	108	93	93	93
		Mean	70.5	73.1	2.4	70.2	72.0	1.7
		SD	18.96	19.14	16.84	18.99	17.88	14.98
		Median	75.0	80.0	0.0	70.0	70.0	0.0
		95% CI	66.9, 74.1	69.5, 76.7	-0.9, 5.6	66.3, 74.2	68.3, 75.7	-1.4, 4.8
		Q1, Q3	60.0, 85.0	60.0, 85.0	-5.0, 10.0	50.0, 85.0	60.0, 90.0	-5.0, 9.0
		Min, Max	10.0, 100.0	5.0, 100.0	-50.0, 50.0	30.0, 100.0	25.0, 100.0	-40.0, 40.0
		Mean Diff (95% CI) [a]			2.4 (-0.9, 5.6)			1.7 (-1.4, 4.8)
		P-value [a]			0.149			0.271
		Mean Diff (95% CI) [b]			0.6 (-3.8, 5.1)			
		P-value [b]			0.781			
		Effect Size (95% CI) [c]			0.03 (-0.18, 0.25)			
	C5D1	N	94	97	94	79	79	79
		Mean	70.5	72.6	1.9	70.3	73.0	2.7
		SD	19.50	18.35	16.29	18.65	17.43	14.70
		Median	75.0	75.0	0.0	70.0	75.0	0.0
		95% CI	66.5, 74.5	68.9, 76.3	-1.4, 5.3	66.1, 74.5	69.1, 76.9	-0.6, 6.0
		Q1, Q3	60.0, 85.0	60.0, 90.0	-5.0, 10.0	51.0, 85.0	65.0, 85.0	-5.0, 10.0
		Min, Max	10.0, 100.0	25.0, 100.0	-55.0, 50.0	30.0, 100.0	20.0, 100.0	-30.0, 40.0
		Mean Diff (95% CI) [a]			1.9 (-1.4, 5.3)			2.7 (-0.6, 6.0)
		P-value [a]			0.255			0.110
		Mean Diff (95% CI) [b]			-0.7 (-5.4, 4.0)			
		P-value [b]			0.754			
		Effect Size (95% CI) [c]			-0.04 (-0.25, 0.18)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C6D1	N	91	94	91	69	69	69
		Mean	71.8	74.8	3.0	70.9	71.1	0.2
		SD	19.54	16.84	15.80	18.94	18.33	15.82
		Median	75.0	80.0	3.0	70.0	75.0	0.0
		95% CI	67.7, 75.9	71.4, 78.3	-0.3, 6.3	66.3, 75.4	66.7, 75.5	-3.6, 4.0
		Q1, Q3	60.0, 85.0	65.0, 88.0	-5.0, 10.0	51.0, 85.0	60.0, 85.0	-5.0, 10.0
		Min, Max	10.0, 100.0	30.0, 100.0	-50.0, 60.0	30.0, 100.0	25.0, 97.0	-40.0, 30.0
		Mean Diff (95% CI) [a]			3.0 (-0.3, 6.3)			0.2 (-3.6, 4.0)
		P-value [a]			0.071			0.897
		Mean Diff (95% CI) [b]			2.8 (-2.2, 7.8)			
		P-value [b]			0.273			
		Effect Size (95% CI) [c]			0.14 (-0.07, 0.35)			
	C7D1	N	76	78	76	53	53	53
		Mean	69.9	74.0	3.7	72.6	74.9	2.3
		SD	19.53	17.93	16.30	18.86	17.33	14.47
		Median	75.0	75.5	5.0	75.0	75.0	0.0
		95% CI	65.4, 74.3	69.9, 78.0	0.0, 7.4	67.4, 77.8	70.1, 79.7	-1.7, 6.3
		Q1, Q3	60.0, 82.5	60.0, 90.0	-5.0, 10.0	60.0, 90.0	60.0, 90.0	-5.0, 10.0
		Min, Max	10.0, 100.0	20.0, 100.0	-60.0, 50.0	30.0, 100.0	40.0, 100.0	-40.0, 45.0
		Mean Diff (95% CI) [a]			3.7 (0.0, 7.4)			2.3 (-1.7, 6.3)
		P-value [a]			0.052			0.248
		Mean Diff (95% CI) [b]			1.4 (-4.2, 6.9)			
		P-value [b]			0.626			
		Effect Size (95% CI) [c]			0.07 (-0.15, 0.28)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C8D1	N	73	75	73	49	49	49
		Mean	70.7	73.6	2.4	72.6	74.6	2.0
		SD	18.85	17.84	15.71	19.03	17.39	14.55
		Median	75.0	80.0	5.0	75.0	80.0	0.0
		95% CI	66.3, 75.1	69.5, 77.7	-1.2, 6.1	67.1, 78.1	69.6, 79.6	-2.2, 6.2
		Q1, Q3	60.0, 85.0	65.0, 86.0	-5.0, 10.0	60.0, 85.0	65.0, 90.0	-5.0, 10.0
		Min, Max	10.0, 100.0	15.0, 100.0	-65.0, 35.0	30.0, 100.0	40.0, 100.0	-40.0, 45.0
		Mean Diff (95% CI) [a]			2.4 (-1.2, 6.1)			2.0 (-2.2, 6.2)
		P-value [a]			0.191			0.346
		Mean Diff (95% CI) [b]			0.4 (-5.1, 6.0)			
		P-value [b]			0.875			
		Effect Size (95% CI) [c]			0.02 (-0.19, 0.24)			
	C9D1	N	57	59	57	41	41	41
		Mean	71.8	73.8	1.4	73.0	72.8	-0.2
		SD	18.35	16.21	13.88	19.44	16.65	14.78
		Median	75.0	75.0	0.0	75.0	74.0	0.0
		95% CI	67.0, 76.7	69.5, 78.0	-2.3, 5.0	66.9, 79.1	67.5, 78.0	-4.9, 4.4
		Q1, Q3	60.0, 85.0	60.0, 88.0	-5.0, 10.0	60.0, 85.0	60.0, 85.0	-5.0, 10.0
		Min, Max	25.0, 100.0	40.0, 100.0	-40.0, 30.0	30.0, 100.0	40.0, 100.0	-35.0, 30.0
		Mean Diff (95% CI) [a]			1.4 (-2.3, 5.0)			-0.2 (-4.9, 4.4)
		P-value [a]			0.465			0.916
		Mean Diff (95% CI) [b]			1.6 (-4.2, 7.4)			
		P-value [b]			0.586			
		Effect Size (95% CI) [c]			0.08 (-0.13, 0.29)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C10D1	N	52	54	52	29	29	29
		Mean	70.7	72.1	0.7	71.1	69.5	-1.6
		SD	18.37	16.81	15.66	19.31	16.80	15.97
		Median	72.5	75.0	0.0	75.0	70.0	-3.0
		95% CI	65.6, 75.8	67.5, 76.7	-3.6, 5.1	63.7, 78.4	63.1, 75.9	-7.6, 4.5
		Q1, Q3	60.0, 85.0	60.0, 85.0	-5.0, 10.0	65.0, 85.0	55.0, 80.0	-9.0, 10.0
		Min, Max	25.0, 100.0	40.0, 100.0	-40.0, 35.0	30.0, 100.0	40.0, 100.0	-35.0, 30.0
		Mean Diff (95% CI) [a]			0.7 (-3.6, 5.1)			-1.6 (-7.6, 4.5)
		P-value [a]			0.738			0.605
		Mean Diff (95% CI) [b]			2.3 (-5.0, 9.6)			
		P-value [b]			0.534			
		Effect Size (95% CI) [c]			0.11 (-0.10, 0.33)			
	C11D1	N	44	45	44	23	23	23
		Mean	70.8	73.6	2.2	78.7	77.6	-1.1
		SD	18.89	16.74	16.13	16.47	14.13	15.12
		Median	75.0	74.0	0.0	80.0	78.0	-3.0
		95% CI	65.1, 76.6	68.6, 78.6	-2.7, 7.1	71.6, 85.9	71.5, 83.7	-7.7, 5.4
		Q1, Q3	60.0, 85.0	65.0, 85.0	-5.0, 10.0	70.0, 95.0	65.0, 90.0	-5.0, 8.0
		Min, Max	25.0, 100.0	40.0, 100.0	-40.0, 55.0	40.0, 100.0	55.0, 100.0	-35.0, 32.0
		Mean Diff (95% CI) [a]			2.2 (-2.7, 7.1)			-1.1 (-7.7, 5.4)
		P-value [a]			0.379			0.723
		Mean Diff (95% CI) [b]			3.3 (-4.8, 11.4)			
		P-value [b]			0.421			
		Effect Size (95% CI) [c]			0.17 (-0.05, 0.38)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C12D1	N	39	40	39	19	19	19
		Mean	70.8	73.5	2.0	79.5	76.5	-3.1
		SD	19.98	17.54	15.76	13.12	13.11	12.71
		Median	75.0	72.5	0.0	80.0	75.0	-3.0
		95% CI	64.4, 77.3	67.9, 79.1	-3.1, 7.1	73.2, 85.9	70.2, 82.8	-9.2, 3.1
		Q1, Q3	60.0, 85.0	62.5, 88.5	-5.0, 10.0	70.0, 85.0	70.0, 85.0	-15.0, 10.0
		Min, Max	25.0, 100.0	40.0, 100.0	-40.0, 52.0	53.0, 100.0	50.0, 95.0	-30.0, 25.0
		Mean Diff (95% CI) [a]			2.0 (-3.1, 7.1)			-3.1 (-9.2, 3.1)
		P-value [a]			0.439			0.309
		Mean Diff (95% CI) [b]			5.0 (-3.3, 13.3)			
		P-value [b]			0.231			
		Effect Size (95% CI) [c]			0.25 (0.04, 0.47)			
	C13D1	N	32	33	32	15	15	15
		Mean	70.7	74.8	3.3	74.9	77.3	2.5
		SD	19.66	15.27	13.77	16.22	12.94	12.92
		Median	75.0	75.0	0.0	75.0	80.0	0.0
		95% CI	63.6, 77.8	69.3, 80.2	-1.7, 8.2	65.9, 83.8	70.2, 84.5	-4.7, 9.6
		Q1, Q3	60.0, 85.0	65.0, 85.0	-5.0, 5.0	65.0, 85.0	70.0, 85.0	-5.0, 10.0
		Min, Max	25.0, 100.0	40.0, 100.0	-15.0, 50.0	40.0, 100.0	55.0, 100.0	-20.0, 30.0
		Mean Diff (95% CI) [a]			3.3 (-1.7, 8.2)			2.5 (-4.7, 9.6)
		P-value [a]			0.192			0.472
		Mean Diff (95% CI) [b]			0.8 (-7.7, 9.3)			
		P-value [b]			0.854			
		Effect Size (95% CI) [c]			0.04 (-0.17, 0.25)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C14D1	N	30	31	30	12	12	12
		Mean	70.3	72.8	1.7	74.0	68.8	-5.2
		SD	19.76	20.00	19.52	16.02	18.17	18.40
		Median	75.0	75.0	0.0	77.5	69.0	-2.5
		95% CI	62.9, 77.6	65.5, 80.2	-5.6, 9.0	63.8, 84.2	57.3, 80.4	-16.9, 6.5
		Q1, Q3	60.0, 85.0	65.0, 85.0	-5.0, 10.0	67.5, 85.0	55.0, 79.0	-17.5, 5.0
		Min, Max	25.0, 100.0	8.0, 100.0	-77.0, 40.0	40.0, 100.0	40.0, 100.0	-35.0, 25.0
		Mean Diff (95% CI) [a]			1.7 (-5.6, 9.0)			-5.2 (-16.9, 6.5)
		P-value [a]			0.643			0.352
		Mean Diff (95% CI) [b]			6.8 (-6.4, 20.1)			
		P-value [b]			0.304			
		Effect Size (95% CI) [c]			0.34 (0.13, 0.56)			
	C15D1	N	26	27	26	13	13	13
		Mean	69.4	73.1	2.7	72.9	68.6	-4.3
		SD	20.31	15.45	12.27	15.82	16.56	20.13
		Median	75.0	70.0	0.0	75.0	70.0	-5.0
		95% CI	61.2, 77.6	67.0, 79.3	-2.3, 7.6	63.4, 82.5	58.6, 78.6	-16.5, 7.9
		Q1, Q3	60.0, 85.0	65.0, 85.0	-5.0, 10.0	65.0, 85.0	60.0, 75.0	-15.0, 5.0
		Min, Max	25.0, 100.0	45.0, 100.0	-10.0, 35.0	40.0, 100.0	40.0, 95.0	-40.0, 34.0
		Mean Diff (95% CI) [a]			2.7 (-2.3, 7.6)			-4.3 (-16.5, 7.9)
		P-value [a]			0.274			0.455
		Mean Diff (95% CI) [b]			7.0 (-3.5, 17.5)			
		P-value [b]			0.185			
		Effect Size (95% CI) [c]			0.35 (0.14, 0.57)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C16D1	N	26	27	26	10	10	10
		Mean	69.3	74.4	4.1	72.3	71.0	-1.3
		SD	20.24	17.49	12.99	18.06	14.49	15.78
		Median	75.0	70.0	0.5	75.0	72.5	0.0
		95% CI	61.2, 77.5	67.5, 81.4	-1.1, 9.4	59.4, 85.2	60.6, 81.4	-12.6, 10.0
		Q1, Q3	60.0, 85.0	65.0, 90.0	-3.0, 10.0	60.0, 85.0	60.0, 75.0	-5.0, 0.0
		Min, Max	25.0, 100.0	40.0, 100.0	-20.0, 35.0	40.0, 100.0	50.0, 100.0	-35.0, 22.0
		Mean Diff (95% CI) [a]			4.1 (-1.1, 9.4)			-1.3 (-12.6, 10.0)
		P-value [a]			0.119			0.800
		Mean Diff (95% CI) [b]			5.4 (-5.0, 15.8)			
		P-value [b]			0.298			
		Effect Size (95% CI) [c]			0.27 (0.06, 0.49)			
	C17D1	N	24	25	24	7	7	7
		Mean	68.8	71.4	1.4	69.0	67.9	-1.1
		SD	20.60	20.81	12.49	17.71	9.06	16.10
		Median	75.0	75.0	0.0	70.0	70.0	0.0
		95% CI	60.1, 77.4	62.8, 79.9	-3.9, 6.7	52.6, 85.4	59.5, 76.2	-16.0, 13.7
		Q1, Q3	55.0, 82.5	60.0, 90.0	-5.0, 10.0	53.0, 85.0	60.0, 70.0	-15.0, 17.0
		Min, Max	25.0, 100.0	30.0, 100.0	-25.0, 35.0	40.0, 85.0	60.0, 85.0	-25.0, 20.0
		Mean Diff (95% CI) [a]			1.4 (-3.9, 6.7)			-1.1 (-16.0, 13.7)
		P-value [a]			0.584			0.857
		Mean Diff (95% CI) [b]			2.6 (-9.1, 14.3)			
		P-value [b]			0.658			
		Effect Size (95% CI) [c]			0.13 (-0.09, 0.34)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C18D1	N	20	21	20	7	7	7
		Mean	68.8	71.5	1.4	75.7	76.0	0.3
		SD	19.99	20.45	10.86	19.46	14.15	9.60
		Median	75.0	75.0	0.0	85.0	75.0	0.0
		95% CI	59.4, 78.1	62.2, 80.8	-3.7, 6.4	57.7, 93.7	62.9, 89.1	-8.6, 9.2
		Q1, Q3	57.5, 80.0	60.0, 90.0	-7.5, 12.5	65.0, 85.0	60.0, 85.0	-5.0, 2.0
		Min, Max	25.0, 100.0	30.0, 100.0	-15.0, 20.0	40.0, 100.0	60.0, 100.0	-10.0, 20.0
		Mean Diff (95% CI) [a]			1.4 (-3.7, 6.4)			0.3 (-8.6, 9.2)
		P-value [a]			0.585			0.940
		Mean Diff (95% CI) [b]			1.1 (-8.5, 10.6)			
		P-value [b]			0.821			
		Effect Size (95% CI) [c]			0.05 (-0.16, 0.27)			
	C19D1	N	19	20	19	6	6	6
		Mean	68.4	71.6	1.7	74.2	67.5	-6.7
		SD	20.48	19.14	11.49	20.84	18.64	12.52
		Median	75.0	72.5	0.0	77.5	70.0	-2.5
		95% CI	58.5, 78.3	62.6, 80.6	-3.9, 7.2	52.3, 96.0	47.9, 87.1	-19.8, 6.5
		Q1, Q3	50.0, 80.0	65.0, 86.0	-9.0, 5.0	65.0, 85.0	55.0, 75.0	-10.0, 0.0
		Min, Max	25.0, 100.0	30.0, 100.0	-10.0, 30.0	40.0, 100.0	40.0, 95.0	-30.0, 5.0
		Mean Diff (95% CI) [a]			1.7 (-3.9, 7.2)			-6.7 (-19.8, 6.5)
		P-value [a]			0.531			0.249
		Mean Diff (95% CI) [b]			8.4 (-3.0, 19.7)			
		P-value [b]			0.142			
		Effect Size (95% CI) [c]			0.42 (0.20, 0.64)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C20D1	N	18	19	18	4	4	4
		Mean	72.5	75.4	1.5	68.8	76.3	7.5
		SD	19.72	17.98	9.51	21.36	13.15	17.08
		Median	75.0	80.0	0.0	75.0	72.5	5.0
		95% CI	62.7, 82.3	66.7, 84.0	-3.2, 6.2	34.8, 102.7	55.3, 97.2	-19.7, 34.7
		Q1, Q3	70.0, 85.0	65.0, 87.0	-5.0, 5.0	52.5, 85.0	67.5, 85.0	-5.0, 20.0
		Min, Max	25.0, 100.0	25.0, 100.0	-10.0, 30.0	40.0, 85.0	65.0, 95.0	-10.0, 30.0
		Mean Diff (95% CI) [a]			1.5 (-3.2, 6.2)			7.5 (-19.7, 34.7)
		P-value [a]			0.513			0.444
		Mean Diff (95% CI) [b]			-6.0 (-18.7, 6.7)			
		P-value [b]			0.335			
		Effect Size (95% CI) [c]			-0.30 (-0.52, -0.09)			
	C21D1	N	17	18	17	4	4	4
		Mean	71.2	73.2	0.4	68.8	72.5	3.8
		SD	19.81	18.24	10.24	21.36	16.58	13.77
		Median	75.0	75.0	0.0	75.0	67.5	2.5
		95% CI	61.0, 81.4	64.1, 82.2	-4.9, 5.7	34.8, 102.7	46.1, 98.9	-18.2, 25.7
		Q1, Q3	70.0, 80.0	65.0, 87.0	-5.0, 5.0	52.5, 85.0	60.0, 85.0	-7.5, 15.0
		Min, Max	25.0, 100.0	25.0, 100.0	-15.0, 20.0	40.0, 85.0	60.0, 95.0	-10.0, 20.0
		Mean Diff (95% CI) [a]			0.4 (-4.9, 5.7)			3.8 (-18.2, 25.7)
		P-value [a]			0.870			0.624
		Mean Diff (95% CI) [b]			-3.3 (-16.0, 9.3)			
		P-value [b]			0.587			
		Effect Size (95% CI) [c]			-0.17 (-0.38, 0.05)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C22D1	N	14	15	14	3	3	3
		Mean	72.1	73.4	-0.6	70.0	75.7	5.7
		SD	19.68	19.43	15.17	25.98	17.79	16.92
		Median	75.0	75.0	1.0	85.0	72.0	10.0
		95% CI	60.8, 83.5	62.6, 84.2	-9.4, 8.1	5.5, 134.5	31.5, 119.8	-36.4, 47.7
		Q1, Q3	70.0, 85.0	65.0, 92.0	-10.0, 5.0	40.0, 85.0	60.0, 95.0	-13.0, 20.0
		Min, Max	25.0, 100.0	40.0, 100.0	-40.0, 22.0	40.0, 85.0	60.0, 95.0	-13.0, 20.0
		Mean Diff (95% CI) [a]			-0.6 (-9.4, 8.1)			5.7 (-36.4, 47.7)
		P-value [a]			0.876			0.621
		Mean Diff (95% CI) [b]			-6.3 (-27.2, 14.6)			
		P-value [b]			0.530			
		Effect Size (95% CI) [c]			-0.32 (-0.53, -0.10)			
	C23D1	N	10	11	10	3	3	3
		Mean	69.0	72.0	0.2	70.0	76.7	6.7
		SD	21.83	19.72	10.45	25.98	17.56	15.28
		Median	72.5	70.0	-2.5	85.0	75.0	10.0
		95% CI	53.4, 84.6	58.7, 85.3	-7.3, 7.7	5.5, 134.5	33.0, 120.3	-31.3, 44.6
		Q1, Q3	70.0, 75.0	65.0, 90.0	-10.0, 5.0	40.0, 85.0	60.0, 95.0	-10.0, 20.0
		Min, Max	25.0, 100.0	35.0, 100.0	-10.0, 22.0	40.0, 85.0	60.0, 95.0	-10.0, 20.0
		Mean Diff (95% CI) [a]			0.2 (-7.3, 7.7)			6.7 (-31.3, 44.6)
		P-value [a]			0.953			0.529
		Mean Diff (95% CI) [b]			-6.5 (-23.1, 10.2)			
		P-value [b]			0.410			
		Effect Size (95% CI) [c]			-0.33 (-0.54, -0.11)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C24D1	N	9	10	9	2	2	2
		Mean	70.6	74.0	0.6	62.5	77.5	15.0
		SD	18.45	18.53	11.58	31.82	24.75	7.07
		Median	75.0	72.5	0.0	62.5	77.5	15.0
		95% CI	56.4, 84.7	60.7, 87.3	-8.3, 9.5	-223.4, 348.4	-144.9, 299.9	-48.5, 78.5
		Q1, Q3	70.0, 75.0	60.0, 90.0	-10.0, 5.0	40.0, 85.0	60.0, 95.0	10.0, 20.0
		Min, Max	25.0, 90.0	40.0, 100.0	-15.0, 20.0	40.0, 85.0	60.0, 95.0	10.0, 20.0
		Mean Diff (95% CI) [a]			0.6 (-8.3, 9.5)			15.0 (-48.5, 78.5)
		P-value [a]			0.889			0.205
		Mean Diff (95% CI) [b]			-14.4 (-34.2, 5.3)			
		P-value [b]			0.132			
		Effect Size (95% CI) [c]			-0.73 (-0.95, -0.51)			
	C25D1	N	8	9	8	0	0	0
		Mean	68.8	71.3	-1.0	NE	NE	NE
		SD	18.85	20.30	9.68	NE	NE	NE
		Median	72.5	70.0	0.0	NE	NE	NE
		95% CI	53.0, 84.5	55.7, 86.9	-9.1, 7.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 75.0	65.0, 87.0	-7.5, 2.5	NE, NE	NE, NE	NE, NE
		Min, Max	25.0, 90.0	30.0, 100.0	-15.0, 17.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			-1.0 (-9.1, 7.1)			NE (NE, NE)
		P-value [a]			0.779			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C26D1	N	7	8	7	1	1	1
		Mean	76.4	79.6	0.3	85.0	95.0	10.0
		SD	8.02	17.39	13.74	NE	NE	NE
		Median	75.0	82.5	0.0	85.0	95.0	10.0
		95% CI	69.0, 83.8	65.1, 94.2	-12.4, 13.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	67.5, 93.5	-10.0, 10.0	85.0, 85.0	95.0, 95.0	10.0, 10.0
		Min, Max	70.0, 90.0	50.0, 100.0	-20.0, 22.0	85.0, 85.0	95.0, 95.0	10.0, 10.0
		Mean Diff (95% CI) [a]			0.3 (-12.4, 13.0)			10.0 (NE, NE)
		P-value [a]			0.958			NE
		Mean Diff (95% CI) [b]			-9.7 (-45.7, 26.2)			
		P-value [b]			0.533			
		Effect Size (95% CI) [c]			-0.49 (-0.71, -0.27)			
	C27D1	N	7	8	7	1	1	1
		Mean	76.4	81.9	2.9	85.0	95.0	10.0
		SD	8.02	14.87	11.13	NE	NE	NE
		Median	75.0	82.5	5.0	85.0	95.0	10.0
		95% CI	69.0, 83.8	69.4, 94.3	-7.4, 13.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	70.0, 95.0	-5.0, 10.0	85.0, 85.0	95.0, 95.0	10.0, 10.0
		Min, Max	70.0, 90.0	60.0, 100.0	-15.0, 20.0	85.0, 85.0	95.0, 95.0	10.0, 10.0
		Mean Diff (95% CI) [a]			2.9 (-7.4, 13.1)			10.0 (NE, NE)
		P-value [a]			0.522			NE
		Mean Diff (95% CI) [b]			-7.1 (-36.2, 22.0)			
		P-value [b]			0.570			
		Effect Size (95% CI) [c]			-0.36 (-0.58, -0.14)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C28D1	N	6	6	6	1	1	1
		Mean	75.0	74.5	-0.5	85.0	95.0	10.0
		SD	7.75	11.55	10.37	NE	NE	NE
		Median	72.5	70.0	0.0	85.0	95.0	10.0
		95% CI	66.9, 83.1	62.4, 86.6	-11.4, 10.4	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 75.0	70.0, 87.0	-5.0, 0.0	85.0, 85.0	95.0, 95.0	10.0, 10.0
		Min, Max	70.0, 90.0	60.0, 90.0	-15.0, 17.0	85.0, 85.0	95.0, 95.0	10.0, 10.0
		Mean Diff (95% CI) [a]			-0.5 (-11.4, 10.4)			10.0 (NE, NE)
		P-value [a]			0.911			NE
		Mean Diff (95% CI) [b]			-10.5 (-39.3, 18.3)			
		P-value [b]			0.392			
		Effect Size (95% CI) [c]			-0.53 (-0.75, -0.31)			
	C29D1	N	4	4	4	1	1	1
		Mean	71.3	71.3	0.0	85.0	65.0	-20.0
		SD	2.50	16.52	18.71	NE	NE	NE
		Median	70.0	72.5	2.5	85.0	65.0	-20.0
		95% CI	67.3, 75.2	45.0, 97.5	-29.8, 29.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 72.5	60.0, 82.5	-12.5, 12.5	85.0, 85.0	65.0, 65.0	-20.0, -20.0
		Min, Max	70.0, 75.0	50.0, 90.0	-25.0, 20.0	85.0, 85.0	65.0, 65.0	-20.0, -20.0
		Mean Diff (95% CI) [a]			0.0 (-29.8, 29.8)			-20.0 (NE, NE)
		P-value [a]			1.000			NE
		Mean Diff (95% CI) [b]			20.0 (-46.6, 86.6)			
		P-value [b]			0.410			
		Effect Size (95% CI) [c]			1.01 (0.78, 1.23)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C30D1	N	4	4	4	1	1	1
		Mean	75.0	76.3	1.3	85.0	40.0	-45.0
		SD	7.07	12.50	11.09	NE	NE	NE
		Median	72.5	77.5	5.0	85.0	40.0	-45.0
		95% CI	63.7, 86.3	56.4, 96.1	-16.4, 18.9	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 80.0	67.5, 85.0	-5.0, 7.5	85.0, 85.0	40.0, 40.0	-45.0, -45.0
		Min, Max	70.0, 85.0	60.0, 90.0	-15.0, 10.0	85.0, 85.0	40.0, 40.0	-45.0, -45.0
		Mean Diff (95% CI) [a]			1.3 (-16.4, 18.9)			-45.0 (NE, NE)
		P-value [a]			0.836			NE
		Mean Diff (95% CI) [b]			46.3 (6.8, 85.7)			
		P-value [b]			0.034			
		Effect Size (95% CI) [c]			2.33 (2.05, 2.61)			
	C31D1	N	2	2	2	1	1	1
		Mean	70.0	76.0	6.0	85.0	65.0	-20.0
		SD	0.00	8.49	8.49	NE	NE	NE
		Median	70.0	76.0	6.0	85.0	65.0	-20.0
		95% CI	70.0, 70.0	-0.2, 152.2	-70.2, 82.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 70.0	70.0, 82.0	0.0, 12.0	85.0, 85.0	65.0, 65.0	-20.0, -20.0
		Min, Max	70.0, 70.0	70.0, 82.0	0.0, 12.0	85.0, 85.0	65.0, 65.0	-20.0, -20.0
		Mean Diff (95% CI) [a]			6.0 (-70.2, 82.2)			-20.0 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			26.0 (-106.0, 158.0)			
		P-value [b]			0.242			
		Effect Size (95% CI) [c]			1.31 (1.07, 1.55)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C32D1	N	2	2	2	1	1	1
		Mean	70.0	83.5	13.5	85.0	75.0	-10.0
		SD	0.00	12.02	12.02	NE	NE	NE
		Median	70.0	83.5	13.5	85.0	75.0	-10.0
		95% CI	70.0, 70.0	-24.5, 191.5	-94.5, 121.5	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 70.0	75.0, 92.0	5.0, 22.0	85.0, 85.0	75.0, 75.0	-10.0, -10.0
		Min, Max	70.0, 70.0	75.0, 92.0	5.0, 22.0	85.0, 85.0	75.0, 75.0	-10.0, -10.0
		Mean Diff (95% CI) [a]			13.5 (-94.5, 121.5)			-10.0 (NE, NE)
		P-value [a]			0.358			NE
		Mean Diff (95% CI) [b]			23.5 (-163.6, 210.6)			
		P-value [b]			0.356			
		Effect Size (95% CI) [c]			1.18 (0.95, 1.42)			
	C33D1	N	2	2	2	1	1	1
		Mean	70.0	77.5	7.5	85.0	70.0	-15.0
		SD	0.00	10.61	10.61	NE	NE	NE
		Median	70.0	77.5	7.5	85.0	70.0	-15.0
		95% CI	70.0, 70.0	-17.8, 172.8	-87.8, 102.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 70.0	70.0, 85.0	0.0, 15.0	85.0, 85.0	70.0, 70.0	-15.0, -15.0
		Min, Max	70.0, 70.0	70.0, 85.0	0.0, 15.0	85.0, 85.0	70.0, 70.0	-15.0, -15.0
		Mean Diff (95% CI) [a]			7.5 (-87.8, 102.8)			-15.0 (NE, NE)
		P-value [a]			0.500			NE
		Mean Diff (95% CI) [b]			22.5 (-142.6, 187.6)			
		P-value [b]			0.333			
		Effect Size (95% CI) [c]			1.13 (0.90, 1.36)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C34D1	N	2	2	2	0	0	0
		Mean	70.0	77.5	7.5	NE	NE	NE
		SD	0.00	17.68	17.68	NE	NE	NE
		Median	70.0	77.5	7.5	NE	NE	NE
		95% CI	70.0, 70.0	-81.3, 236.3	-151.3, 166.3	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 70.0	65.0, 90.0	-5.0, 20.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 70.0	65.0, 90.0	-5.0, 20.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			7.5 (-151.3, 166.3)			NE (NE, NE)
		P-value [a]			0.656			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C35D1	N	2	2	2	0	0	0
		Mean	70.0	78.0	8.0	NE	NE	NE
		SD	0.00	18.38	18.38	NE	NE	NE
		Median	70.0	78.0	8.0	NE	NE	NE
		95% CI	70.0, 70.0	-87.2, 243.2	-157.2, 173.2	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 70.0	65.0, 91.0	-5.0, 21.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 70.0	65.0, 91.0	-5.0, 21.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			8.0 (-157.2, 173.2)			NE (NE, NE)
		P-value [a]			0.649			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C36D1	N	3	3	3	0	0	0
		Mean	75.0	84.3	9.3	NE	NE	NE
		SD	8.66	21.36	17.21	NE	NE	NE
		Median	70.0	93.0	15.0	NE	NE	NE
		95% CI	53.5, 96.5	31.3, 137.4	-33.4, 52.1	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	60.0, 100.0	-10.0, 23.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 85.0	60.0, 100.0	-10.0, 23.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			9.3 (-33.4, 52.1)			NE (NE, NE)
		P-value [a]			0.447			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C37D1	N	3	3	3	0	0	0
		Mean	75.0	86.0	11.0	NE	NE	NE
		SD	8.66	13.89	11.53	NE	NE	NE
		Median	70.0	93.0	10.0	NE	NE	NE
		95% CI	53.5, 96.5	51.5, 120.5	-17.6, 39.6	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	70.0, 95.0	0.0, 23.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 85.0	70.0, 95.0	0.0, 23.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			11.0 (-17.6, 39.6)			NE (NE, NE)
		P-value [a]			0.240			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C38D1	N	2	2	2	0	0	0
		Mean	77.5	91.0	13.5	NE	NE	NE
		SD	10.61	5.66	4.95	NE	NE	NE
		Median	77.5	91.0	13.5	NE	NE	NE
		95% CI	-17.8, 172.8	40.2, 141.8	-31.0, 58.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	87.0, 95.0	10.0, 17.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 85.0	87.0, 95.0	10.0, 17.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			13.5 (-31.0, 58.0)			NE (NE, NE)
		P-value [a]			0.161			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C39D1	N	2	2	2	0	0	0
		Mean	77.5	95.0	17.5	NE	NE	NE
		SD	10.61	0.00	10.61	NE	NE	NE
		Median	77.5	95.0	17.5	NE	NE	NE
		95% CI	-17.8, 172.8	95.0, 95.0	-77.8, 112.8	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	95.0, 95.0	10.0, 25.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 85.0	95.0, 95.0	10.0, 25.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			17.5 (-77.8, 112.8)			NE (NE, NE)
		P-value [a]			0.258			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C40D1	N	2	2	2	0	0	0
		Mean	77.5	91.0	13.5	NE	NE	NE
		SD	10.61	5.66	4.95	NE	NE	NE
		Median	77.5	91.0	13.5	NE	NE	NE
		95% CI	-17.8, 172.8	40.2, 141.8	-31.0, 58.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	87.0, 95.0	10.0, 17.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 85.0	87.0, 95.0	10.0, 17.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			13.5 (-31.0, 58.0)			NE (NE, NE)
		P-value [a]			0.161			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C41D1	N	2	2	2	0	0	0
		Mean	77.5	87.5	10.0	NE	NE	NE
		SD	10.61	10.61	0.00	NE	NE	NE
		Median	77.5	87.5	10.0	NE	NE	NE
		95% CI	-17.8, 172.8	-7.8, 182.8	10.0, 10.0	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 85.0	80.0, 95.0	10.0, 10.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 85.0	80.0, 95.0	10.0, 10.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			10.0 (10.0, 10.0)			NE (NE, NE)
		P-value [a]			<.001			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	C42D1	N	1	1	1	0	0	0
		Mean	70.0	88.0	18.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	70.0	88.0	18.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 70.0	88.0, 88.0	18.0, 18.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 70.0	88.0, 88.0	18.0, 18.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			18.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			
	C43D1	N	1	1	1	0	0	0
		Mean	70.0	92.0	22.0	NE	NE	NE
		SD	NE	NE	NE	NE	NE	NE
		Median	70.0	92.0	22.0	NE	NE	NE
		95% CI	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE	NE, NE
		Q1, Q3	70.0, 70.0	92.0, 92.0	22.0, 22.0	NE, NE	NE, NE	NE, NE
		Min, Max	70.0, 70.0	92.0, 92.0	22.0, 22.0	NE, NE	NE, NE	NE, NE
		Mean Diff (95% CI) [a]			22.0 (NE, NE)			NE (NE, NE)
		P-value [a]			NE			NE
		Mean Diff (95% CI) [b]			NE (NE, NE)			
		P-value [b]			NE			
		Effect Size (95% CI) [c]			NE (NE, NE)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.3.2
EQ-5D VAS and Change from Baseline by Visit
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

			SG (N=175)			TPC (N=164)		
Domain	Visit	Statistics	Baseline	Post-Baseline	Change from Baseline	Baseline	Post-Baseline	Change from Baseline
	EOT	N	123	126	123	125	125	125
		Mean	70.6	64.9	-5.4	70.0	63.3	-6.7
		SD	19.14	22.34	20.15	19.37	21.99	21.17
		Median	75.0	70.0	-5.0	75.0	65.0	-5.0
		95% CI	67.1, 74.0	60.9, 68.8	-9.0, -1.8	66.6, 73.4	59.4, 67.2	-10.4, -2.9
		Q1, Q3	60.0, 80.0	50.0, 85.0	-15.0, 5.0	60.0, 85.0	50.0, 80.0	-15.0, 5.0
		Min, Max	6.0, 100.0	2.0, 100.0	-70.0, 50.0	20.0, 100.0	0.0, 98.0	-80.0, 50.0
		Mean Diff (95% CI) [a]			-5.4 (-9.0, -1.8)			-6.7 (-10.4, -2.9)
		P-value [a]			0.003			0.001
		Mean Diff (95% CI) [b]			1.2 (-3.9, 6.4)			
		P-value [b]			0.635			
		Effect Size (95% CI) [c]			0.06 (-0.15, 0.28)			
	Long Term Follow-up	N	14	14	14	9	9	9
		Mean	76.8	73.1	-3.7	76.7	68.7	-8.0
		SD	15.27	21.29	10.77	15.61	26.24	13.27
		Median	75.0	78.5	-2.5	80.0	80.0	-5.0
		95% CI	68.0, 85.6	60.8, 85.4	-9.9, 2.5	64.7, 88.7	48.5, 88.8	-18.2, 2.2
		Q1, Q3	70.0, 85.0	55.0, 90.0	-10.0, 5.0	70.0, 85.0	60.0, 85.0	-10.0, 0.0
		Min, Max	45.0, 100.0	30.0, 100.0	-20.0, 11.0	50.0, 100.0	15.0, 95.0	-35.0, 10.0
		Mean Diff (95% CI) [a]			-3.7 (-9.9, 2.5)			-8.0 (-18.2, 2.2)
		P-value [a]			0.219			0.108
		Mean Diff (95% CI) [b]			4.3 (-6.2, 14.8)			
		P-value [b]			0.404			
		Effect Size (95% CI) [c]			0.22 (0.00, 0.43)			

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. CI = Confidence Interval; Diff = Difference; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; NE = Not Estimable; SD = standard deviation; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] The mean difference, 95% CI and p-value are calculated based on a paired, 2-sided t-test for the within-group change from baseline.
[b] The mean difference, 95% CI and p-value are calculated based on a pooled 2-sample, 2-sided t-test for the difference in mean change from baseline between SG and TPC.
[c] Effect sizes and CIs of difference in mean change between SG and TPC are estimated using the Hedges' g.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Decreased Appetite Severity	Baseline		N=177	N=179	N=356
		None	96 (54.2%)	95 (53.1%)	191 (53.7%)
		Mild	42 (23.7%)	45 (25.1%)	87 (24.4%)
		Moderate	23 (13.0%)	25 (14.0%)	48 (13.5%)
		Severe	12 (6.8%)	13 (7.3%)	25 (7.0%)
		Very Severe	4 (2.3%)	1 (0.6%)	5 (1.4%)
	C2D1		N=163	N=150	N=313
		None	72 (44.2%)	65 (43.3%)	137 (43.8%)
		Mild	43 (26.4%)	32 (21.3%)	75 (24.0%)
		Moderate	30 (18.4%)	39 (26.0%)	69 (22.0%)
		Severe	14 (8.6%)	13 (8.7%)	27 (8.6%)
		Very Severe	4 (2.5%)	1 (0.7%)	5 (1.6%)
	C3D1		N=132	N=106	N=238
		None	77 (58.3%)	55 (51.9%)	132 (55.5%)
		Mild	25 (18.9%)	25 (23.6%)	50 (21.0%)
		Moderate	21 (15.9%)	17 (16.0%)	38 (16.0%)
		Severe	7 (5.3%)	6 (5.7%)	13 (5.5%)
		Very Severe	2 (1.5%)	3 (2.8%)	5 (2.1%)
	C4D1		N=118	N=97	N=215
		None	71 (60.2%)	50 (51.5%)	121 (56.3%)
		Mild	27 (22.9%)	23 (23.7%)	50 (23.3%)
		Moderate	16 (13.6%)	20 (20.6%)	36 (16.7%)
		Severe	2 (1.7%)	4 (4.1%)	6 (2.8%)
		Very Severe	2 (1.7%)	0 (0.0%)	2 (0.9%)
	C5D1		N=106	N=83	N=189
		None	65 (61.3%)	50 (60.2%)	115 (60.8%)
		Mild	29 (27.4%)	13 (15.7%)	42 (22.2%)
		Moderate	10 (9.4%)	15 (18.1%)	25 (13.2%)
		Severe	1 (0.9%)	5 (6.0%)	6 (3.2%)
		Very Severe	1 (0.9%)	0 (0.0%)	1 (0.5%)
	C6D1		N=102	N=74	N=176
		None	65 (63.7%)	40 (54.1%)	105 (59.7%)
		Mild	17 (16.7%)	19 (25.7%)	36 (20.5%)
		Moderate	17 (16.7%)	10 (13.5%)	27 (15.3%)
		Severe	2 (2.0%)	4 (5.4%)	6 (3.4%)
		Very Severe	1 (1.0%)	1 (1.4%)	2 (1.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=85	N=56	N=141
		None	55 (64.7%)	37 (66.1%)	92 (65.2%)
		Mild	20 (23.5%)	16 (28.6%)	36 (25.5%)
		Moderate	9 (10.6%)	3 (5.4%)	12 (8.5%)
		Severe	1 (1.2%)	0 (0.0%)	1 (0.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=80	N=50	N=130
		None	53 (66.3%)	35 (70.0%)	88 (67.7%)
		Mild	19 (23.8%)	10 (20.0%)	29 (22.3%)
		Moderate	6 (7.5%)	4 (8.0%)	10 (7.7%)
		Severe	2 (2.5%)	0 (0.0%)	2 (1.5%)
		Very Severe	0 (0.0%)	1 (2.0%)	1 (0.8%)
	C9D1		N=64	N=42	N=106
		None	42 (65.6%)	29 (69.0%)	71 (67.0%)
		Mild	14 (21.9%)	8 (19.0%)	22 (20.8%)
		Moderate	4 (6.3%)	4 (9.5%)	8 (7.5%)
		Severe	3 (4.7%)	1 (2.4%)	4 (3.8%)
		Very Severe	1 (1.6%)	0 (0.0%)	1 (0.9%)
	C10D1		N=57	N=31	N=88
		None	41 (71.9%)	17 (54.8%)	58 (65.9%)
		Mild	11 (19.3%)	7 (22.6%)	18 (20.5%)
		Moderate	4 (7.0%)	6 (19.4%)	10 (11.4%)
		Severe	1 (1.8%)	1 (3.2%)	2 (2.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=49	N=24	N=73
		None	34 (69.4%)	18 (75.0%)	52 (71.2%)
		Mild	12 (24.5%)	4 (16.7%)	16 (21.9%)
		Moderate	2 (4.1%)	1 (4.2%)	3 (4.1%)
		Severe	1 (2.0%)	1 (4.2%)	2 (2.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=43	N=20	N=63
		None	33 (76.7%)	15 (75.0%)	48 (76.2%)
		Mild	5 (11.6%)	3 (15.0%)	8 (12.7%)
		Moderate	4 (9.3%)	2 (10.0%)	6 (9.5%)
		Severe	1 (2.3%)	0 (0.0%)	1 (1.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=36	N=15	N=51
		None	24 (66.7%)	9 (60.0%)	33 (64.7%)
		Mild	7 (19.4%)	6 (40.0%)	13 (25.5%)
		Moderate	4 (11.1%)	0 (0.0%)	4 (7.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (2.8%)	0 (0.0%)	1 (2.0%)
	C14D1		N=35	N=13	N=48
		None	25 (71.4%)	7 (53.8%)	32 (66.7%)
		Mild	9 (25.7%)	4 (30.8%)	13 (27.1%)
		Moderate	1 (2.9%)	2 (15.4%)	3 (6.3%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=30	N=14	N=44
		None	22 (73.3%)	8 (57.1%)	30 (68.2%)
		Mild	5 (16.7%)	6 (42.9%)	11 (25.0%)
		Moderate	3 (10.0%)	0 (0.0%)	3 (6.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C16D1		N=30	N=11	N=41
		None	21 (70.0%)	6 (54.5%)	27 (65.9%)
		Mild	6 (20.0%)	5 (45.5%)	11 (26.8%)
		Moderate	2 (6.7%)	0 (0.0%)	2 (4.9%)
		Severe	1 (3.3%)	0 (0.0%)	1 (2.4%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=28	N=7	N=35
		None	21 (75.0%)	3 (42.9%)	24 (68.6%)
		Mild	3 (10.7%)	4 (57.1%)	7 (20.0%)
		Moderate	4 (14.3%)	0 (0.0%)	4 (11.4%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		None	18 (78.3%)	3 (42.9%)	21 (70.0%)
		Mild	2 (8.7%)	4 (57.1%)	6 (20.0%)
		Moderate	3 (13.0%)	0 (0.0%)	3 (10.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=21	N=6	N=27
		None	17 (81.0%)	3 (50.0%)	20 (74.1%)
		Mild	4 (19.0%)	3 (50.0%)	7 (25.9%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		None	16 (80.0%)	4 (100.0%)	20 (83.3%)
		Mild	3 (15.0%)	0 (0.0%)	3 (12.5%)
		Moderate	1 (5.0%)	0 (0.0%)	1 (4.2%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		None	14 (77.8%)	3 (75.0%)	17 (77.3%)
		Mild	3 (16.7%)	1 (25.0%)	4 (18.2%)
		Moderate	1 (5.6%)	0 (0.0%)	1 (4.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C22D1		N=15	N=3	N=18
		None	13 (86.7%)	2 (66.7%)	15 (83.3%)
		Mild	1 (6.7%)	1 (33.3%)	2 (11.1%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (6.7%)	0 (0.0%)	1 (5.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		None	7 (70.0%)	3 (100.0%)	10 (76.9%)
		Mild	2 (20.0%)	0 (0.0%)	2 (15.4%)
		Moderate	1 (10.0%)	0 (0.0%)	1 (7.7%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		None	8 (80.0%)	1 (50.0%)	9 (75.0%)
		Mild	1 (10.0%)	1 (50.0%)	2 (16.7%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (10.0%)	0 (0.0%)	1 (8.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=9	N=0	N=9
		None	7 (77.8%)	0 (NE)	7 (77.8%)
		Mild	1 (11.1%)	0 (NE)	1 (11.1%)
		Moderate	1 (11.1%)	0 (NE)	1 (11.1%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		None	6 (75.0%)	1 (100.0%)	7 (77.8%)
		Mild	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		None	7 (87.5%)	1 (100.0%)	8 (88.9%)
		Mild	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		None	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		None	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Mild	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Moderate	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		None	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		None	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Mild	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		None	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Mild	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		None	3 (100.0%)	0 (0.0%)	3 (75.0%)
		Mild	0 (0.0%)	1 (100.0%)	1 (25.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		None	3 (100.0%)	0 (NE)	3 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=3	N=0	N=3
		None	3 (100.0%)	0 (NE)	3 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=137	N=131	N=268
		None	67 (48.9%)	60 (45.8%)	127 (47.4%)
		Mild	32 (23.4%)	27 (20.6%)	59 (22.0%)
		Moderate	23 (16.8%)	34 (26.0%)	57 (21.3%)
		Severe	11 (8.0%)	6 (4.6%)	17 (6.3%)
		Very Severe	4 (2.9%)	4 (3.1%)	8 (3.0%)
	Long Term Follow-up		N=15	N=9	N=24
		None	8 (53.3%)	4 (44.4%)	12 (50.0%)
		Mild	2 (13.3%)	2 (22.2%)	4 (16.7%)
		Moderate	4 (26.7%)	0 (0.0%)	4 (16.7%)
		Severe	1 (6.7%)	3 (33.3%)	4 (16.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
Decreased Appetite Interference	Baseline		N=175	N=176	N=351
		Not At All	124 (70.9%)	127 (72.2%)	251 (71.5%)
		A Little Bit	28 (16.0%)	29 (16.5%)	57 (16.2%)
		Somewhat	12 (6.9%)	13 (7.4%)	25 (7.1%)
		Quite A Bit	10 (5.7%)	6 (3.4%)	16 (4.6%)
		Very Much	1 (0.6%)	1 (0.6%)	2 (0.6%)
	C2D1		N=162	N=144	N=306
		Not At All	108 (66.7%)	90 (62.5%)	198 (64.7%)
		A Little Bit	21 (13.0%)	34 (23.6%)	55 (18.0%)
		Somewhat	21 (13.0%)	15 (10.4%)	36 (11.8%)
		Quite A Bit	10 (6.2%)	4 (2.8%)	14 (4.6%)
		Very Much	2 (1.2%)	1 (0.7%)	3 (1.0%)
	C3D1		N=130	N=103	N=233
		Not At All	97 (74.6%)	76 (73.8%)	173 (74.2%)
		A Little Bit	18 (13.8%)	15 (14.6%)	33 (14.2%)
		Somewhat	12 (9.2%)	9 (8.7%)	21 (9.0%)
		Quite A Bit	3 (2.3%)	2 (1.9%)	5 (2.1%)
		Very Much	0 (0.0%)	1 (1.0%)	1 (0.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=115	N=93	N=208
		Not At All	89 (77.4%)	63 (67.7%)	152 (73.1%)
		A Little Bit	17 (14.8%)	17 (18.3%)	34 (16.3%)
		Somewhat	5 (4.3%)	11 (11.8%)	16 (7.7%)
		Quite A Bit	3 (2.6%)	2 (2.2%)	5 (2.4%)
		Very Much	1 (0.9%)	0 (0.0%)	1 (0.5%)
	C5D1		N=103	N=78	N=181
		Not At All	79 (76.7%)	57 (73.1%)	136 (75.1%)
		A Little Bit	15 (14.6%)	13 (16.7%)	28 (15.5%)
		Somewhat	7 (6.8%)	7 (9.0%)	14 (7.7%)
		Quite A Bit	2 (1.9%)	1 (1.3%)	3 (1.7%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C6D1		N=97	N=69	N=166
		Not At All	69 (71.1%)	47 (68.1%)	116 (69.9%)
		A Little Bit	21 (21.6%)	11 (15.9%)	32 (19.3%)
		Somewhat	4 (4.1%)	9 (13.0%)	13 (7.8%)
		Quite A Bit	2 (2.1%)	2 (2.9%)	4 (2.4%)
		Very Much	1 (1.0%)	0 (0.0%)	1 (0.6%)
	C7D1		N=84	N=52	N=136
		Not At All	73 (86.9%)	42 (80.8%)	115 (84.6%)
		A Little Bit	6 (7.1%)	7 (13.5%)	13 (9.6%)
		Somewhat	5 (6.0%)	3 (5.8%)	8 (5.9%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=76	N=44	N=120
		Not At All	61 (80.3%)	37 (84.1%)	98 (81.7%)
		A Little Bit	9 (11.8%)	4 (9.1%)	13 (10.8%)
		Somewhat	3 (3.9%)	2 (4.5%)	5 (4.2%)
		Quite A Bit	3 (3.9%)	1 (2.3%)	4 (3.3%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C9D1		N=60	N=41	N=101
		Not At All	49 (81.7%)	33 (80.5%)	82 (81.2%)
		A Little Bit	7 (11.7%)	5 (12.2%)	12 (11.9%)
		Somewhat	1 (1.7%)	3 (7.3%)	4 (4.0%)
		Quite A Bit	1 (1.7%)	0 (0.0%)	1 (1.0%)
		Very Much	2 (3.3%)	0 (0.0%)	2 (2.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=54	N=29	N=83
		Not At All	45 (83.3%)	23 (79.3%)	68 (81.9%)
		A Little Bit	6 (11.1%)	1 (3.4%)	7 (8.4%)
		Somewhat	2 (3.7%)	5 (17.2%)	7 (8.4%)
		Quite A Bit	1 (1.9%)	0 (0.0%)	1 (1.2%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=47	N=24	N=71
		Not At All	39 (83.0%)	21 (87.5%)	60 (84.5%)
		A Little Bit	5 (10.6%)	1 (4.2%)	6 (8.5%)
		Somewhat	2 (4.3%)	1 (4.2%)	3 (4.2%)
		Quite A Bit	1 (2.1%)	1 (4.2%)	2 (2.8%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=41	N=20	N=61
		Not At All	34 (82.9%)	17 (85.0%)	51 (83.6%)
		A Little Bit	4 (9.8%)	2 (10.0%)	6 (9.8%)
		Somewhat	2 (4.9%)	1 (5.0%)	3 (4.9%)
		Quite A Bit	1 (2.4%)	0 (0.0%)	1 (1.6%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C13D1		N=31	N=15	N=46
		Not At All	23 (74.2%)	13 (86.7%)	36 (78.3%)
		A Little Bit	6 (19.4%)	2 (13.3%)	8 (17.4%)
		Somewhat	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Quite A Bit	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=34	N=13	N=47
		Not At All	28 (82.4%)	12 (92.3%)	40 (85.1%)
		A Little Bit	6 (17.6%)	1 (7.7%)	7 (14.9%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=29	N=13	N=42
		Not At All	24 (82.8%)	10 (76.9%)	34 (81.0%)
		A Little Bit	4 (13.8%)	3 (23.1%)	7 (16.7%)
		Somewhat	1 (3.4%)	0 (0.0%)	1 (2.4%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=28	N=11	N=39
		Not At All	24 (85.7%)	7 (63.6%)	31 (79.5%)
		A Little Bit	3 (10.7%)	4 (36.4%)	7 (17.9%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	1 (3.6%)	0 (0.0%)	1 (2.6%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=27	N=7	N=34
		Not At All	23 (85.2%)	5 (71.4%)	28 (82.4%)
		A Little Bit	2 (7.4%)	2 (28.6%)	4 (11.8%)
		Somewhat	1 (3.7%)	0 (0.0%)	1 (2.9%)
		Quite A Bit	1 (3.7%)	0 (0.0%)	1 (2.9%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Not At All	20 (87.0%)	6 (85.7%)	26 (86.7%)
		A Little Bit	1 (4.3%)	0 (0.0%)	1 (3.3%)
		Somewhat	2 (8.7%)	1 (14.3%)	3 (10.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C19D1		N=19	N=5	N=24
		Not At All	17 (89.5%)	3 (60.0%)	20 (83.3%)
		A Little Bit	2 (10.5%)	2 (40.0%)	4 (16.7%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=19	N=4	N=23
		Not At All	16 (84.2%)	4 (100.0%)	20 (87.0%)
		A Little Bit	2 (10.5%)	0 (0.0%)	2 (8.7%)
		Somewhat	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		Not At All	17 (94.4%)	3 (75.0%)	20 (90.9%)
		A Little Bit	0 (0.0%)	1 (25.0%)	1 (4.5%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	1 (5.6%)	0 (0.0%)	1 (4.5%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=14	N=3	N=17
		Not At All	13 (92.9%)	3 (100.0%)	16 (94.1%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	1 (7.1%)	0 (0.0%)	1 (5.9%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Not At All	8 (80.0%)	3 (100.0%)	11 (84.6%)
		A Little Bit	1 (10.0%)	0 (0.0%)	1 (7.7%)
		Somewhat	1 (10.0%)	0 (0.0%)	1 (7.7%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		Not At All	7 (70.0%)	2 (100.0%)	9 (75.0%)
		A Little Bit	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	2 (20.0%)	0 (0.0%)	2 (16.7%)
	C25D1		N=8	N=0	N=8
		Not At All	7 (87.5%)	0 (NE)	7 (87.5%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	1 (12.5%)	0 (NE)	1 (12.5%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Not At All	7 (87.5%)	1 (100.0%)	8 (88.9%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		Not At All	8 (100.0%)	1 (100.0%)	9 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=6	N=1	N=7
		Not At All	6 (100.0%)	1 (100.0%)	7 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=3	N=1	N=4
		Not At All	3 (100.0%)	1 (100.0%)	4 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Not At All	4 (100.0%)	1 (100.0%)	5 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=1	N=1	N=2
		Not At All	1 (100.0%)	0 (0.0%)	1 (50.0%)
		A Little Bit	0 (0.0%)	1 (100.0%)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Not At All	1 (50.0%)	0 (0.0%)	1 (33.3%)
		A Little Bit	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Not At All	3 (100.0%)	1 (100.0%)	4 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=130	N=124	N=254
		Not At All	85 (65.4%)	78 (62.9%)	163 (64.2%)
		A Little Bit	22 (16.9%)	21 (16.9%)	43 (16.9%)
		Somewhat	11 (8.5%)	15 (12.1%)	26 (10.2%)
		Quite A Bit	11 (8.5%)	8 (6.5%)	19 (7.5%)
		Very Much	1 (0.8%)	2 (1.6%)	3 (1.2%)
	Long Term Follow-up		N=15	N=9	N=24
		Not At All	8 (53.3%)	6 (66.7%)	14 (58.3%)
		A Little Bit	7 (46.7%)	0 (0.0%)	7 (29.2%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	3 (33.3%)	3 (12.5%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Nausea Frequency	Baseline		N=177	N=180	N=357
		Never	119 (67.2%)	114 (63.3%)	233 (65.3%)
		Rarely	28 (15.8%)	34 (18.9%)	62 (17.4%)
		Occasionally	20 (11.3%)	20 (11.1%)	40 (11.2%)
		Frequently	10 (5.6%)	10 (5.6%)	20 (5.6%)
		Almost Constantly	0 (0.0%)	2 (1.1%)	2 (0.6%)
	C2D1		N=163	N=150	N=313
		Never	78 (47.9%)	84 (56.0%)	162 (51.8%)
		Rarely	40 (24.5%)	29 (19.3%)	69 (22.0%)
		Occasionally	35 (21.5%)	24 (16.0%)	59 (18.8%)
		Frequently	10 (6.1%)	11 (7.3%)	21 (6.7%)
		Almost Constantly	0 (0.0%)	2 (1.3%)	2 (0.6%)
	C3D1		N=131	N=105	N=236
		Never	74 (56.5%)	69 (65.7%)	143 (60.6%)
		Rarely	30 (22.9%)	15 (14.3%)	45 (19.1%)
		Occasionally	20 (15.3%)	15 (14.3%)	35 (14.8%)
		Frequently	6 (4.6%)	5 (4.8%)	11 (4.7%)
		Almost Constantly	1 (0.8%)	1 (1.0%)	2 (0.8%)
	C4D1		N=119	N=97	N=216
		Never	69 (58.0%)	71 (73.2%)	140 (64.8%)
		Rarely	29 (24.4%)	15 (15.5%)	44 (20.4%)
		Occasionally	17 (14.3%)	9 (9.3%)	26 (12.0%)
		Frequently	3 (2.5%)	1 (1.0%)	4 (1.9%)
		Almost Constantly	1 (0.8%)	1 (1.0%)	2 (0.9%)
	C5D1		N=105	N=83	N=188
		Never	66 (62.9%)	58 (69.9%)	124 (66.0%)
		Rarely	21 (20.0%)	12 (14.5%)	33 (17.6%)
		Occasionally	17 (16.2%)	13 (15.7%)	30 (16.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	1 (1.0%)	0 (0.0%)	1 (0.5%)
	C6D1		N=102	N=74	N=176
		Never	64 (62.7%)	51 (68.9%)	115 (65.3%)
		Rarely	22 (21.6%)	11 (14.9%)	33 (18.8%)
		Occasionally	14 (13.7%)	8 (10.8%)	22 (12.5%)
		Frequently	2 (2.0%)	4 (5.4%)	6 (3.4%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=85	N=56	N=141
		Never	52 (61.2%)	44 (78.6%)	96 (68.1%)
		Rarely	24 (28.2%)	7 (12.5%)	31 (22.0%)
		Occasionally	8 (9.4%)	4 (7.1%)	12 (8.5%)
		Frequently	0 (0.0%)	1 (1.8%)	1 (0.7%)
		Almost Constantly	1 (1.2%)	0 (0.0%)	1 (0.7%)
	C8D1		N=80	N=51	N=131
		Never	51 (63.8%)	40 (78.4%)	91 (69.5%)
		Rarely	22 (27.5%)	7 (13.7%)	29 (22.1%)
		Occasionally	5 (6.3%)	3 (5.9%)	8 (6.1%)
		Frequently	2 (2.5%)	1 (2.0%)	3 (2.3%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C9D1		N=64	N=42	N=106
		Never	42 (65.6%)	36 (85.7%)	78 (73.6%)
		Rarely	15 (23.4%)	4 (9.5%)	19 (17.9%)
		Occasionally	5 (7.8%)	1 (2.4%)	6 (5.7%)
		Frequently	1 (1.6%)	1 (2.4%)	2 (1.9%)
		Almost Constantly	1 (1.6%)	0 (0.0%)	1 (0.9%)
	C10D1		N=57	N=31	N=88
		Never	39 (68.4%)	24 (77.4%)	63 (71.6%)
		Rarely	13 (22.8%)	4 (12.9%)	17 (19.3%)
		Occasionally	2 (3.5%)	3 (9.7%)	5 (5.7%)
		Frequently	3 (5.3%)	0 (0.0%)	3 (3.4%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=49	N=24	N=73
		Never	33 (67.3%)	18 (75.0%)	51 (69.9%)
		Rarely	10 (20.4%)	5 (20.8%)	15 (20.5%)
		Occasionally	4 (8.2%)	1 (4.2%)	5 (6.8%)
		Frequently	2 (4.1%)	0 (0.0%)	2 (2.7%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=43	N=20	N=63
		Never	26 (60.5%)	17 (85.0%)	43 (68.3%)
		Rarely	9 (20.9%)	2 (10.0%)	11 (17.5%)
		Occasionally	7 (16.3%)	1 (5.0%)	8 (12.7%)
		Frequently	1 (2.3%)	0 (0.0%)	1 (1.6%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=36	N=15	N=51
		Never	22 (61.1%)	12 (80.0%)	34 (66.7%)
		Rarely	6 (16.7%)	1 (6.7%)	7 (13.7%)
		Occasionally	7 (19.4%)	2 (13.3%)	9 (17.6%)
		Frequently	1 (2.8%)	0 (0.0%)	1 (2.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=35	N=13	N=48
		Never	23 (65.7%)	9 (69.2%)	32 (66.7%)
		Rarely	6 (17.1%)	1 (7.7%)	7 (14.6%)
		Occasionally	6 (17.1%)	3 (23.1%)	9 (18.8%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=30	N=14	N=44
		Never	24 (80.0%)	11 (78.6%)	35 (79.5%)
		Rarely	2 (6.7%)	3 (21.4%)	5 (11.4%)
		Occasionally	3 (10.0%)	0 (0.0%)	3 (6.8%)
		Frequently	1 (3.3%)	0 (0.0%)	1 (2.3%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C16D1		N=30	N=11	N=41
		Never	18 (60.0%)	8 (72.7%)	26 (63.4%)
		Rarely	9 (30.0%)	1 (9.1%)	10 (24.4%)
		Occasionally	3 (10.0%)	2 (18.2%)	5 (12.2%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=28	N=7	N=35
		Never	19 (67.9%)	6 (85.7%)	25 (71.4%)
		Rarely	5 (17.9%)	1 (14.3%)	6 (17.1%)
		Occasionally	2 (7.1%)	0 (0.0%)	2 (5.7%)
		Frequently	2 (7.1%)	0 (0.0%)	2 (5.7%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Never	16 (69.6%)	6 (85.7%)	22 (73.3%)
		Rarely	3 (13.0%)	0 (0.0%)	3 (10.0%)
		Occasionally	4 (17.4%)	1 (14.3%)	5 (16.7%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=20	N=6	N=26
		Never	14 (70.0%)	4 (66.7%)	18 (69.2%)
		Rarely	5 (25.0%)	2 (33.3%)	7 (26.9%)
		Occasionally	1 (5.0%)	0 (0.0%)	1 (3.8%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		Never	15 (75.0%)	3 (75.0%)	18 (75.0%)
		Rarely	3 (15.0%)	1 (25.0%)	4 (16.7%)
		Occasionally	2 (10.0%)	0 (0.0%)	2 (8.3%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		Never	15 (83.3%)	2 (50.0%)	17 (77.3%)
		Rarely	2 (11.1%)	1 (25.0%)	3 (13.6%)
		Occasionally	1 (5.6%)	1 (25.0%)	2 (9.1%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C22D1		N=15	N=3	N=18
		Never	11 (73.3%)	2 (66.7%)	13 (72.2%)
		Rarely	3 (20.0%)	0 (0.0%)	3 (16.7%)
		Occasionally	1 (6.7%)	1 (33.3%)	2 (11.1%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Never	8 (80.0%)	2 (66.7%)	10 (76.9%)
		Rarely	0 (0.0%)	1 (33.3%)	1 (7.7%)
		Occasionally	2 (20.0%)	0 (0.0%)	2 (15.4%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		Never	7 (70.0%)	1 (50.0%)	8 (66.7%)
		Rarely	2 (20.0%)	0 (0.0%)	2 (16.7%)
		Occasionally	0 (0.0%)	1 (50.0%)	1 (8.3%)
		Frequently	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=9	N=0	N=9
		Never	7 (77.8%)	0 (NE)	7 (77.8%)
		Rarely	1 (11.1%)	0 (NE)	1 (11.1%)
		Occasionally	1 (11.1%)	0 (NE)	1 (11.1%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Never	7 (87.5%)	1 (100.0%)	8 (88.9%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		Never	8 (100.0%)	1 (100.0%)	9 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		Never	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Never	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Never	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		Never	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Never	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Never	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		Never	2 (66.7%)	0 (NE)	2 (66.7%)
		Rarely	1 (33.3%)	0 (NE)	1 (33.3%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Never	3 (100.0%)	0 (NE)	3 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=3	N=0	N=3
		Never	3 (100.0%)	0 (NE)	3 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=137	N=131	N=268
		Never	80 (58.4%)	83 (63.4%)	163 (60.8%)
		Rarely	34 (24.8%)	30 (22.9%)	64 (23.9%)
		Occasionally	15 (10.9%)	9 (6.9%)	24 (9.0%)
		Frequently	8 (5.8%)	7 (5.3%)	15 (5.6%)
		Almost Constantly	0 (0.0%)	2 (1.5%)	2 (0.7%)
	Long Term		N=15	N=9	N=24
	Follow-up	Never	11 (73.3%)	4 (44.4%)	15 (62.5%)
		Rarely	1 (6.7%)	1 (11.1%)	2 (8.3%)
		Occasionally	3 (20.0%)	3 (33.3%)	6 (25.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	1 (11.1%)	1 (4.2%)
Nausea Severity	Baseline		N=171	N=174	N=345
		None	124 (72.5%)	116 (66.7%)	240 (69.6%)
		Mild	27 (15.8%)	38 (21.8%)	65 (18.8%)
		Moderate	14 (8.2%)	17 (9.8%)	31 (9.0%)
		Severe	6 (3.5%)	3 (1.7%)	9 (2.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C2D1		N=160	N=139	N=299
		None	83 (51.9%)	83 (59.7%)	166 (55.5%)
		Mild	50 (31.3%)	30 (21.6%)	80 (26.8%)
		Moderate	22 (13.8%)	24 (17.3%)	46 (15.4%)
		Severe	5 (3.1%)	2 (1.4%)	7 (2.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C3D1		N=131	N=101	N=232
		None	83 (63.4%)	65 (64.4%)	148 (63.8%)
		Mild	33 (25.2%)	23 (22.8%)	56 (24.1%)
		Moderate	11 (8.4%)	10 (9.9%)	21 (9.1%)
		Severe	3 (2.3%)	3 (3.0%)	6 (2.6%)
		Very Severe	1 (0.8%)	0 (0.0%)	1 (0.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=114	N=95	N=209
		None	69 (60.5%)	71 (74.7%)	140 (67.0%)
		Mild	34 (29.8%)	12 (12.6%)	46 (22.0%)
		Moderate	7 (6.1%)	9 (9.5%)	16 (7.7%)
		Severe	2 (1.8%)	3 (3.2%)	5 (2.4%)
		Very Severe	2 (1.8%)	0 (0.0%)	2 (1.0%)
	C5D1		N=103	N=78	N=181
		None	65 (63.1%)	56 (71.8%)	121 (66.9%)
		Mild	27 (26.2%)	18 (23.1%)	45 (24.9%)
		Moderate	10 (9.7%)	4 (5.1%)	14 (7.7%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (1.0%)	0 (0.0%)	1 (0.6%)
	C6D1		N=95	N=70	N=165
		None	58 (61.1%)	53 (75.7%)	111 (67.3%)
		Mild	29 (30.5%)	12 (17.1%)	41 (24.8%)
		Moderate	7 (7.4%)	3 (4.3%)	10 (6.1%)
		Severe	1 (1.1%)	2 (2.9%)	3 (1.8%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C7D1		N=81	N=50	N=131
		None	54 (66.7%)	43 (86.0%)	97 (74.0%)
		Mild	20 (24.7%)	4 (8.0%)	24 (18.3%)
		Moderate	7 (8.6%)	2 (4.0%)	9 (6.9%)
		Severe	0 (0.0%)	1 (2.0%)	1 (0.8%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=76	N=44	N=120
		None	51 (67.1%)	34 (77.3%)	85 (70.8%)
		Mild	20 (26.3%)	8 (18.2%)	28 (23.3%)
		Moderate	4 (5.3%)	1 (2.3%)	5 (4.2%)
		Severe	0 (0.0%)	1 (2.3%)	1 (0.8%)
		Very Severe	1 (1.3%)	0 (0.0%)	1 (0.8%)
	C9D1		N=60	N=40	N=100
		None	43 (71.7%)	34 (85.0%)	77 (77.0%)
		Mild	13 (21.7%)	4 (10.0%)	17 (17.0%)
		Moderate	3 (5.0%)	2 (5.0%)	5 (5.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (1.7%)	0 (0.0%)	1 (1.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=55	N=29	N=84
		None	38 (69.1%)	23 (79.3%)	61 (72.6%)
		Mild	13 (23.6%)	5 (17.2%)	18 (21.4%)
		Moderate	4 (7.3%)	1 (3.4%)	5 (6.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=48	N=24	N=72
		None	34 (70.8%)	20 (83.3%)	54 (75.0%)
		Mild	9 (18.8%)	4 (16.7%)	13 (18.1%)
		Moderate	4 (8.3%)	0 (0.0%)	4 (5.6%)
		Severe	1 (2.1%)	0 (0.0%)	1 (1.4%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=40	N=19	N=59
		None	28 (70.0%)	17 (89.5%)	45 (76.3%)
		Mild	9 (22.5%)	1 (5.3%)	10 (16.9%)
		Moderate	2 (5.0%)	1 (5.3%)	3 (5.1%)
		Severe	1 (2.5%)	0 (0.0%)	1 (1.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C13D1		N=31	N=14	N=45
		None	19 (61.3%)	12 (85.7%)	31 (68.9%)
		Mild	6 (19.4%)	2 (14.3%)	8 (17.8%)
		Moderate	5 (16.1%)	0 (0.0%)	5 (11.1%)
		Severe	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=34	N=13	N=47
		None	26 (76.5%)	10 (76.9%)	36 (76.6%)
		Mild	6 (17.6%)	3 (23.1%)	9 (19.1%)
		Moderate	2 (5.9%)	0 (0.0%)	2 (4.3%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=29	N=13	N=42
		None	23 (79.3%)	12 (92.3%)	35 (83.3%)
		Mild	2 (6.9%)	1 (7.7%)	3 (7.1%)
		Moderate	4 (13.8%)	0 (0.0%)	4 (9.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=29	N=11	N=40
		None	19 (65.5%)	8 (72.7%)	27 (67.5%)
		Mild	10 (34.5%)	1 (9.1%)	11 (27.5%)
		Moderate	0 (0.0%)	2 (18.2%)	2 (5.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=27	N=7	N=34
		None	18 (66.7%)	7 (100.0%)	25 (73.5%)
		Mild	7 (25.9%)	0 (0.0%)	7 (20.6%)
		Moderate	2 (7.4%)	0 (0.0%)	2 (5.9%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=22	N=7	N=29
		None	18 (81.8%)	6 (85.7%)	24 (82.8%)
		Mild	2 (9.1%)	1 (14.3%)	3 (10.3%)
		Moderate	1 (4.5%)	0 (0.0%)	1 (3.4%)
		Severe	1 (4.5%)	0 (0.0%)	1 (3.4%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C19D1		N=21	N=5	N=26
		None	16 (76.2%)	4 (80.0%)	20 (76.9%)
		Mild	4 (19.0%)	1 (20.0%)	5 (19.2%)
		Moderate	1 (4.8%)	0 (0.0%)	1 (3.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=18	N=4	N=22
		None	14 (77.8%)	4 (100.0%)	18 (81.8%)
		Mild	4 (22.2%)	0 (0.0%)	4 (18.2%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=17	N=4	N=21
		None	15 (88.2%)	2 (50.0%)	17 (81.0%)
		Mild	2 (11.8%)	1 (25.0%)	3 (14.3%)
		Moderate	0 (0.0%)	1 (25.0%)	1 (4.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=14	N=3	N=17
		None	12 (85.7%)	2 (66.7%)	14 (82.4%)
		Mild	2 (14.3%)	1 (33.3%)	3 (17.6%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		None	8 (80.0%)	2 (66.7%)	10 (76.9%)
		Mild	1 (10.0%)	1 (33.3%)	2 (15.4%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (10.0%)	0 (0.0%)	1 (7.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		None	8 (80.0%)	1 (50.0%)	9 (75.0%)
		Mild	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Moderate	0 (0.0%)	1 (50.0%)	1 (8.3%)
		Severe	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=8	N=0	N=8
		None	6 (75.0%)	0 (NE)	6 (75.0%)
		Mild	2 (25.0%)	0 (NE)	2 (25.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		None	7 (87.5%)	1 (100.0%)	8 (88.9%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		None	8 (100.0%)	1 (100.0%)	9 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=6	N=1	N=7
		None	6 (100.0%)	1 (100.0%)	7 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=2	N=1	N=3
		None	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		None	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=1	N=1	N=2
		None	1 (100.0%)	1 (100.0%)	2 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		None	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		None	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=125	N=123	N=248
		None	75 (60.0%)	80 (65.0%)	155 (62.5%)
		Mild	32 (25.6%)	27 (22.0%)	59 (23.8%)
		Moderate	8 (6.4%)	11 (8.9%)	19 (7.7%)
		Severe	7 (5.6%)	3 (2.4%)	10 (4.0%)
		Very Severe	3 (2.4%)	2 (1.6%)	5 (2.0%)
	Long Term		N=13	N=9	N=22
	Follow-up	None	11 (84.6%)	5 (55.6%)	16 (72.7%)
		Mild	1 (7.7%)	2 (22.2%)	3 (13.6%)
		Moderate	1 (7.7%)	1 (11.1%)	2 (9.1%)
		Severe	0 (0.0%)	1 (11.1%)	1 (4.5%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Vomiting Frequency	Baseline		N=177	N=180	N=357
		Never	155 (87.6%)	162 (90.0%)	317 (88.8%)
		Rarely	11 (6.2%)	6 (3.3%)	17 (4.8%)
		Occasionally	10 (5.6%)	8 (4.4%)	18 (5.0%)
		Frequently	1 (0.6%)	4 (2.2%)	5 (1.4%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C2D1		N=163	N=150	N=313
		Never	141 (86.5%)	131 (87.3%)	272 (86.9%)
		Rarely	11 (6.7%)	10 (6.7%)	21 (6.7%)
		Occasionally	10 (6.1%)	8 (5.3%)	18 (5.8%)
		Frequently	1 (0.6%)	1 (0.7%)	2 (0.6%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C3D1		N=132	N=106	N=238
		Never	116 (87.9%)	97 (91.5%)	213 (89.5%)
		Rarely	9 (6.8%)	5 (4.7%)	14 (5.9%)
		Occasionally	6 (4.5%)	4 (3.8%)	10 (4.2%)
		Frequently	1 (0.8%)	0 (0.0%)	1 (0.4%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C4D1		N=119	N=97	N=216
		Never	106 (89.1%)	88 (90.7%)	194 (89.8%)
		Rarely	8 (6.7%)	6 (6.2%)	14 (6.5%)
		Occasionally	5 (4.2%)	2 (2.1%)	7 (3.2%)
		Frequently	0 (0.0%)	1 (1.0%)	1 (0.5%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C5D1		N=106	N=83	N=189
		Never	94 (88.7%)	77 (92.8%)	171 (90.5%)
		Rarely	10 (9.4%)	4 (4.8%)	14 (7.4%)
		Occasionally	1 (0.9%)	2 (2.4%)	3 (1.6%)
		Frequently	1 (0.9%)	0 (0.0%)	1 (0.5%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C6D1		N=102	N=74	N=176
		Never	90 (88.2%)	70 (94.6%)	160 (90.9%)
		Rarely	7 (6.9%)	1 (1.4%)	8 (4.5%)
		Occasionally	4 (3.9%)	2 (2.7%)	6 (3.4%)
		Frequently	1 (1.0%)	0 (0.0%)	1 (0.6%)
		Almost Constantly	0 (0.0%)	1 (1.4%)	1 (0.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=85	N=55	N=140
		Never	81 (95.3%)	53 (96.4%)	134 (95.7%)
		Rarely	3 (3.5%)	2 (3.6%)	5 (3.6%)
		Occasionally	1 (1.2%)	0 (0.0%)	1 (0.7%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=80	N=51	N=131
		Never	74 (92.5%)	50 (98.0%)	124 (94.7%)
		Rarely	3 (3.8%)	1 (2.0%)	4 (3.1%)
		Occasionally	2 (2.5%)	0 (0.0%)	2 (1.5%)
		Frequently	1 (1.3%)	0 (0.0%)	1 (0.8%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C9D1		N=64	N=42	N=106
		Never	57 (89.1%)	42 (100.0%)	99 (93.4%)
		Rarely	4 (6.3%)	0 (0.0%)	4 (3.8%)
		Occasionally	2 (3.1%)	0 (0.0%)	2 (1.9%)
		Frequently	1 (1.6%)	0 (0.0%)	1 (0.9%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C10D1		N=57	N=31	N=88
		Never	51 (89.5%)	28 (90.3%)	79 (89.8%)
		Rarely	6 (10.5%)	2 (6.5%)	8 (9.1%)
		Occasionally	0 (0.0%)	1 (3.2%)	1 (1.1%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=49	N=24	N=73
		Never	44 (89.8%)	24 (100.0%)	68 (93.2%)
		Rarely	3 (6.1%)	0 (0.0%)	3 (4.1%)
		Occasionally	1 (2.0%)	0 (0.0%)	1 (1.4%)
		Frequently	1 (2.0%)	0 (0.0%)	1 (1.4%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=43	N=20	N=63
		Never	37 (86.0%)	19 (95.0%)	56 (88.9%)
		Rarely	3 (7.0%)	0 (0.0%)	3 (4.8%)
		Occasionally	1 (2.3%)	1 (5.0%)	2 (3.2%)
		Frequently	2 (4.7%)	0 (0.0%)	2 (3.2%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=36	N=15	N=51
		Never	33 (91.7%)	15 (100.0%)	48 (94.1%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	1 (2.8%)	0 (0.0%)	1 (2.0%)
		Frequently	2 (5.6%)	0 (0.0%)	2 (3.9%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=35	N=13	N=48
		Never	32 (91.4%)	13 (100.0%)	45 (93.8%)
		Rarely	2 (5.7%)	0 (0.0%)	2 (4.2%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	1 (2.9%)	0 (0.0%)	1 (2.1%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=30	N=14	N=44
		Never	28 (93.3%)	14 (100.0%)	42 (95.5%)
		Rarely	1 (3.3%)	0 (0.0%)	1 (2.3%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	1 (3.3%)	0 (0.0%)	1 (2.3%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C16D1		N=30	N=11	N=41
		Never	25 (83.3%)	11 (100.0%)	36 (87.8%)
		Rarely	4 (13.3%)	0 (0.0%)	4 (9.8%)
		Occasionally	1 (3.3%)	0 (0.0%)	1 (2.4%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=28	N=7	N=35
		Never	25 (89.3%)	7 (100.0%)	32 (91.4%)
		Rarely	2 (7.1%)	0 (0.0%)	2 (5.7%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	1 (3.6%)	0 (0.0%)	1 (2.9%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Never	22 (95.7%)	7 (100.0%)	29 (96.7%)
		Rarely	1 (4.3%)	0 (0.0%)	1 (3.3%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=20	N=6	N=26
		Never	18 (90.0%)	6 (100.0%)	24 (92.3%)
		Rarely	2 (10.0%)	0 (0.0%)	2 (7.7%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		Never	19 (95.0%)	4 (100.0%)	23 (95.8%)
		Rarely	1 (5.0%)	0 (0.0%)	1 (4.2%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		Never	18 (100.0%)	4 (100.0%)	22 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C22D1		N=15	N=3	N=18
		Never	15 (100.0%)	3 (100.0%)	18 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Never	9 (90.0%)	3 (100.0%)	12 (92.3%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	1 (10.0%)	0 (0.0%)	1 (7.7%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		Never	9 (90.0%)	2 (100.0%)	11 (91.7%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=9	N=0	N=9
		Never	9 (100.0%)	0 (NE)	9 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Never	7 (87.5%)	1 (100.0%)	8 (88.9%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		Never	8 (100.0%)	1 (100.0%)	9 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		Never	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Never	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Never	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		Never	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Never	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Never	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		Never	2 (66.7%)	0 (NE)	2 (66.7%)
		Rarely	1 (33.3%)	0 (NE)	1 (33.3%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Never	3 (100.0%)	0 (NE)	3 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=3	N=0	N=3
		Never	3 (100.0%)	0 (NE)	3 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=137	N=132	N=269
		Never	111 (81.0%)	113 (85.6%)	224 (83.3%)
		Rarely	13 (9.5%)	9 (6.8%)	22 (8.2%)
		Occasionally	9 (6.6%)	7 (5.3%)	16 (5.9%)
		Frequently	3 (2.2%)	3 (2.3%)	6 (2.2%)
		Almost Constantly	1 (0.7%)	0 (0.0%)	1 (0.4%)
	Long Term Follow-up		N=15	N=9	N=24
		Never	13 (86.7%)	7 (77.8%)	20 (83.3%)
		Rarely	0 (0.0%)	1 (11.1%)	1 (4.2%)
		Occasionally	2 (13.3%)	0 (0.0%)	2 (8.3%)
		Frequently	0 (0.0%)	1 (11.1%)	1 (4.2%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vomiting Severity	Baseline		N=173	N=173	N=346
		None	152 (87.9%)	157 (90.8%)	309 (89.3%)
		Mild	10 (5.8%)	8 (4.6%)	18 (5.2%)
		Moderate	9 (5.2%)	6 (3.5%)	15 (4.3%)
		Severe	2 (1.2%)	2 (1.2%)	4 (1.2%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C2D1		N=159	N=140	N=299
		None	136 (85.5%)	123 (87.9%)	259 (86.6%)
		Mild	13 (8.2%)	11 (7.9%)	24 (8.0%)
		Moderate	6 (3.8%)	5 (3.6%)	11 (3.7%)
		Severe	4 (2.5%)	1 (0.7%)	5 (1.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C3D1		N=130	N=100	N=230
		None	114 (87.7%)	92 (92.0%)	206 (89.6%)
		Mild	6 (4.6%)	5 (5.0%)	11 (4.8%)
		Moderate	5 (3.8%)	2 (2.0%)	7 (3.0%)
		Severe	5 (3.8%)	1 (1.0%)	6 (2.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=113	N=94	N=207
		None	102 (90.3%)	85 (90.4%)	187 (90.3%)
		Mild	8 (7.1%)	6 (6.4%)	14 (6.8%)
		Moderate	1 (0.9%)	3 (3.2%)	4 (1.9%)
		Severe	2 (1.8%)	0 (0.0%)	2 (1.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C5D1		N=101	N=78	N=179
		None	89 (88.1%)	72 (92.3%)	161 (89.9%)
		Mild	9 (8.9%)	4 (5.1%)	13 (7.3%)
		Moderate	2 (2.0%)	2 (2.6%)	4 (2.2%)
		Severe	1 (1.0%)	0 (0.0%)	1 (0.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C6D1		N=93	N=69	N=162
		None	82 (88.2%)	65 (94.2%)	147 (90.7%)
		Mild	8 (8.6%)	3 (4.3%)	11 (6.8%)
		Moderate	3 (3.2%)	0 (0.0%)	3 (1.9%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	1 (1.4%)	1 (0.6%)
	C7D1		N=79	N=49	N=128
		None	77 (97.5%)	47 (95.9%)	124 (96.9%)
		Mild	1 (1.3%)	2 (4.1%)	3 (2.3%)
		Moderate	1 (1.3%)	0 (0.0%)	1 (0.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=74	N=44	N=118
		None	68 (91.9%)	43 (97.7%)	111 (94.1%)
		Mild	4 (5.4%)	0 (0.0%)	4 (3.4%)
		Moderate	2 (2.7%)	0 (0.0%)	2 (1.7%)
		Severe	0 (0.0%)	1 (2.3%)	1 (0.8%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C9D1		N=58	N=40	N=98
		None	51 (87.9%)	40 (100.0%)	91 (92.9%)
		Mild	5 (8.6%)	0 (0.0%)	5 (5.1%)
		Moderate	1 (1.7%)	0 (0.0%)	1 (1.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (1.7%)	0 (0.0%)	1 (1.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=52	N=29	N=81
		None	46 (88.5%)	26 (89.7%)	72 (88.9%)
		Mild	5 (9.6%)	2 (6.9%)	7 (8.6%)
		Moderate	1 (1.9%)	1 (3.4%)	2 (2.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=47	N=23	N=70
		None	43 (91.5%)	23 (100.0%)	66 (94.3%)
		Mild	1 (2.1%)	0 (0.0%)	1 (1.4%)
		Moderate	2 (4.3%)	0 (0.0%)	2 (2.9%)
		Severe	1 (2.1%)	0 (0.0%)	1 (1.4%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=38	N=19	N=57
		None	33 (86.8%)	18 (94.7%)	51 (89.5%)
		Mild	2 (5.3%)	0 (0.0%)	2 (3.5%)
		Moderate	3 (7.9%)	1 (5.3%)	4 (7.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C13D1		N=32	N=14	N=46
		None	29 (90.6%)	14 (100.0%)	43 (93.5%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	1 (3.1%)	0 (0.0%)	1 (2.2%)
		Severe	2 (6.3%)	0 (0.0%)	2 (4.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=33	N=13	N=46
		None	30 (90.9%)	13 (100.0%)	43 (93.5%)
		Mild	2 (6.1%)	0 (0.0%)	2 (4.3%)
		Moderate	1 (3.0%)	0 (0.0%)	1 (2.2%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=28	N=12	N=40
		None	26 (92.9%)	12 (100.0%)	38 (95.0%)
		Mild	1 (3.6%)	0 (0.0%)	1 (2.5%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (3.6%)	0 (0.0%)	1 (2.5%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=28	N=11	N=39
		None	23 (82.1%)	11 (100.0%)	34 (87.2%)
		Mild	3 (10.7%)	0 (0.0%)	3 (7.7%)
		Moderate	2 (7.1%)	0 (0.0%)	2 (5.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=27	N=7	N=34
		None	24 (88.9%)	7 (100.0%)	31 (91.2%)
		Mild	2 (7.4%)	0 (0.0%)	2 (5.9%)
		Moderate	1 (3.7%)	0 (0.0%)	1 (2.9%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		None	21 (91.3%)	7 (100.0%)	28 (93.3%)
		Mild	2 (8.7%)	0 (0.0%)	2 (6.7%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C19D1		N=21	N=5	N=26
		None	19 (90.5%)	5 (100.0%)	24 (92.3%)
		Mild	2 (9.5%)	0 (0.0%)	2 (7.7%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=19	N=4	N=23
		None	18 (94.7%)	4 (100.0%)	22 (95.7%)
		Mild	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=17	N=4	N=21
		None	17 (100.0%)	4 (100.0%)	21 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=14	N=3	N=17
		None	14 (100.0%)	3 (100.0%)	17 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		None	9 (90.0%)	3 (100.0%)	12 (92.3%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (10.0%)	0 (0.0%)	1 (7.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		None	8 (80.0%)	2 (100.0%)	10 (83.3%)
		Mild	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=8	N=0	N=8
		None	8 (100.0%)	0 (NE)	8 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		None	7 (87.5%)	1 (100.0%)	8 (88.9%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		None	8 (100.0%)	1 (100.0%)	9 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=6	N=1	N=7
		None	6 (100.0%)	1 (100.0%)	7 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=3	N=1	N=4
		None	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		None	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=1	N=1	N=2
		None	1 (100.0%)	1 (100.0%)	2 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		None	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		None	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=2	N=0	N=2
		None	1 (50.0%)	0 (NE)	1 (50.0%)
		Mild	1 (50.0%)	0 (NE)	1 (50.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		None	3 (100.0%)	0 (NE)	3 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=122	N=120	N=242
		None	97 (79.5%)	103 (85.8%)	200 (82.6%)
		Mild	12 (9.8%)	10 (8.3%)	22 (9.1%)
		Moderate	9 (7.4%)	4 (3.3%)	13 (5.4%)
		Severe	2 (1.6%)	1 (0.8%)	3 (1.2%)
		Very Severe	2 (1.6%)	2 (1.7%)	4 (1.7%)
	Long Term Follow-up		N=13	N=9	N=22
		None	12 (92.3%)	7 (77.8%)	19 (86.4%)
		Mild	1 (7.7%)	1 (11.1%)	2 (9.1%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	1 (11.1%)	1 (4.5%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Constipation Severity	Baseline		N=177	N=180	N=357
		None	100 (56.5%)	111 (61.7%)	211 (59.1%)
		Mild	45 (25.4%)	38 (21.1%)	83 (23.2%)
		Moderate	22 (12.4%)	19 (10.6%)	41 (11.5%)
		Severe	8 (4.5%)	11 (6.1%)	19 (5.3%)
		Very Severe	2 (1.1%)	1 (0.6%)	3 (0.8%)
	C2D1		N=163	N=150	N=313
		None	87 (53.4%)	78 (52.0%)	165 (52.7%)
		Mild	40 (24.5%)	39 (26.0%)	79 (25.2%)
		Moderate	25 (15.3%)	23 (15.3%)	48 (15.3%)
		Severe	9 (5.5%)	5 (3.3%)	14 (4.5%)
		Very Severe	2 (1.2%)	5 (3.3%)	7 (2.2%)
	C3D1		N=132	N=106	N=238
		None	79 (59.8%)	69 (65.1%)	148 (62.2%)
		Mild	31 (23.5%)	21 (19.8%)	52 (21.8%)
		Moderate	20 (15.2%)	12 (11.3%)	32 (13.4%)
		Severe	2 (1.5%)	3 (2.8%)	5 (2.1%)
		Very Severe	0 (0.0%)	1 (0.9%)	1 (0.4%)
	C4D1		N=119	N=97	N=216
		None	74 (62.2%)	63 (64.9%)	137 (63.4%)
		Mild	21 (17.6%)	19 (19.6%)	40 (18.5%)
		Moderate	20 (16.8%)	10 (10.3%)	30 (13.9%)
		Severe	3 (2.5%)	5 (5.2%)	8 (3.7%)
		Very Severe	1 (0.8%)	0 (0.0%)	1 (0.5%)
	C5D1		N=106	N=82	N=188
		None	71 (67.0%)	48 (58.5%)	119 (63.3%)
		Mild	23 (21.7%)	26 (31.7%)	49 (26.1%)
		Moderate	8 (7.5%)	4 (4.9%)	12 (6.4%)
		Severe	4 (3.8%)	2 (2.4%)	6 (3.2%)
		Very Severe	0 (0.0%)	2 (2.4%)	2 (1.1%)
	C6D1		N=102	N=74	N=176
		None	67 (65.7%)	44 (59.5%)	111 (63.1%)
		Mild	21 (20.6%)	20 (27.0%)	41 (23.3%)
		Moderate	12 (11.8%)	6 (8.1%)	18 (10.2%)
		Severe	2 (2.0%)	4 (5.4%)	6 (3.4%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=84	N=55	N=139
		None	60 (71.4%)	37 (67.3%)	97 (69.8%)
		Mild	12 (14.3%)	10 (18.2%)	22 (15.8%)
		Moderate	11 (13.1%)	6 (10.9%)	17 (12.2%)
		Severe	1 (1.2%)	1 (1.8%)	2 (1.4%)
		Very Severe	0 (0.0%)	1 (1.8%)	1 (0.7%)
	C8D1		N=79	N=51	N=130
		None	49 (62.0%)	32 (62.7%)	81 (62.3%)
		Mild	15 (19.0%)	9 (17.6%)	24 (18.5%)
		Moderate	13 (16.5%)	8 (15.7%)	21 (16.2%)
		Severe	2 (2.5%)	2 (3.9%)	4 (3.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C9D1		N=64	N=42	N=106
		None	41 (64.1%)	28 (66.7%)	69 (65.1%)
		Mild	10 (15.6%)	7 (16.7%)	17 (16.0%)
		Moderate	10 (15.6%)	3 (7.1%)	13 (12.3%)
		Severe	3 (4.7%)	3 (7.1%)	6 (5.7%)
		Very Severe	0 (0.0%)	1 (2.4%)	1 (0.9%)
	C10D1		N=57	N=31	N=88
		None	32 (56.1%)	19 (61.3%)	51 (58.0%)
		Mild	9 (15.8%)	5 (16.1%)	14 (15.9%)
		Moderate	10 (17.5%)	5 (16.1%)	15 (17.0%)
		Severe	6 (10.5%)	2 (6.5%)	8 (9.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=49	N=24	N=73
		None	31 (63.3%)	14 (58.3%)	45 (61.6%)
		Mild	12 (24.5%)	4 (16.7%)	16 (21.9%)
		Moderate	3 (6.1%)	5 (20.8%)	8 (11.0%)
		Severe	1 (2.0%)	1 (4.2%)	2 (2.7%)
		Very Severe	2 (4.1%)	0 (0.0%)	2 (2.7%)
	C12D1		N=43	N=20	N=63
		None	26 (60.5%)	14 (70.0%)	40 (63.5%)
		Mild	8 (18.6%)	4 (20.0%)	12 (19.0%)
		Moderate	7 (16.3%)	2 (10.0%)	9 (14.3%)
		Severe	1 (2.3%)	0 (0.0%)	1 (1.6%)
		Very Severe	1 (2.3%)	0 (0.0%)	1 (1.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=36	N=15	N=51
		None	18 (50.0%)	9 (60.0%)	27 (52.9%)
		Mild	11 (30.6%)	4 (26.7%)	15 (29.4%)
		Moderate	4 (11.1%)	2 (13.3%)	6 (11.8%)
		Severe	3 (8.3%)	0 (0.0%)	3 (5.9%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=35	N=13	N=48
		None	19 (54.3%)	8 (61.5%)	27 (56.3%)
		Mild	7 (20.0%)	3 (23.1%)	10 (20.8%)
		Moderate	4 (11.4%)	1 (7.7%)	5 (10.4%)
		Severe	4 (11.4%)	1 (7.7%)	5 (10.4%)
		Very Severe	1 (2.9%)	0 (0.0%)	1 (2.1%)
	C15D1		N=30	N=14	N=44
		None	18 (60.0%)	8 (57.1%)	26 (59.1%)
		Mild	6 (20.0%)	4 (28.6%)	10 (22.7%)
		Moderate	4 (13.3%)	2 (14.3%)	6 (13.6%)
		Severe	1 (3.3%)	0 (0.0%)	1 (2.3%)
		Very Severe	1 (3.3%)	0 (0.0%)	1 (2.3%)
	C16D1		N=30	N=11	N=41
		None	19 (63.3%)	5 (45.5%)	24 (58.5%)
		Mild	6 (20.0%)	4 (36.4%)	10 (24.4%)
		Moderate	3 (10.0%)	1 (9.1%)	4 (9.8%)
		Severe	2 (6.7%)	0 (0.0%)	2 (4.9%)
		Very Severe	0 (0.0%)	1 (9.1%)	1 (2.4%)
	C17D1		N=28	N=7	N=35
		None	17 (60.7%)	3 (42.9%)	20 (57.1%)
		Mild	8 (28.6%)	3 (42.9%)	11 (31.4%)
		Moderate	2 (7.1%)	0 (0.0%)	2 (5.7%)
		Severe	1 (3.6%)	1 (14.3%)	2 (5.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		None	12 (52.2%)	4 (57.1%)	16 (53.3%)
		Mild	7 (30.4%)	2 (28.6%)	9 (30.0%)
		Moderate	1 (4.3%)	1 (14.3%)	2 (6.7%)
		Severe	2 (8.7%)	0 (0.0%)	2 (6.7%)
		Very Severe	1 (4.3%)	0 (0.0%)	1 (3.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=21	N=6	N=27
		None	9 (42.9%)	1 (16.7%)	10 (37.0%)
		Mild	8 (38.1%)	4 (66.7%)	12 (44.4%)
		Moderate	2 (9.5%)	0 (0.0%)	2 (7.4%)
		Severe	2 (9.5%)	1 (16.7%)	3 (11.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		None	11 (55.0%)	1 (25.0%)	12 (50.0%)
		Mild	8 (40.0%)	2 (50.0%)	10 (41.7%)
		Moderate	1 (5.0%)	1 (25.0%)	2 (8.3%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		None	12 (66.7%)	1 (25.0%)	13 (59.1%)
		Mild	4 (22.2%)	2 (50.0%)	6 (27.3%)
		Moderate	1 (5.6%)	0 (0.0%)	1 (4.5%)
		Severe	1 (5.6%)	1 (25.0%)	2 (9.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C22D1		N=15	N=3	N=18
		None	9 (60.0%)	1 (33.3%)	10 (55.6%)
		Mild	4 (26.7%)	1 (33.3%)	5 (27.8%)
		Moderate	1 (6.7%)	1 (33.3%)	2 (11.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (6.7%)	0 (0.0%)	1 (5.6%)
	C23D1		N=10	N=3	N=13
		None	8 (80.0%)	1 (33.3%)	9 (69.2%)
		Mild	0 (0.0%)	1 (33.3%)	1 (7.7%)
		Moderate	1 (10.0%)	1 (33.3%)	2 (15.4%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (10.0%)	0 (0.0%)	1 (7.7%)
	C24D1		N=10	N=2	N=12
		None	5 (50.0%)	1 (50.0%)	6 (50.0%)
		Mild	2 (20.0%)	1 (50.0%)	3 (25.0%)
		Moderate	3 (30.0%)	0 (0.0%)	3 (25.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=9	N=0	N=9
		None	5 (55.6%)	0 (NE)	5 (55.6%)
		Mild	3 (33.3%)	0 (NE)	3 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	1 (11.1%)	0 (NE)	1 (11.1%)
	C26D1		N=8	N=1	N=9
		None	6 (75.0%)	1 (100.0%)	7 (77.8%)
		Mild	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		None	5 (62.5%)	1 (100.0%)	6 (66.7%)
		Mild	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Moderate	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		None	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Mild	2 (28.6%)	0 (0.0%)	2 (25.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		None	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		None	3 (75.0%)	0 (0.0%)	3 (60.0%)
		Mild	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		None	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Mild	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		None	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Mild	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		None	3 (100.0%)	0 (0.0%)	3 (75.0%)
		Mild	0 (0.0%)	1 (100.0%)	1 (25.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		None	1 (50.0%)	0 (NE)	1 (50.0%)
		Mild	1 (50.0%)	0 (NE)	1 (50.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=137	N=131	N=268
		None	84 (61.3%)	83 (63.4%)	167 (62.3%)
		Mild	25 (18.2%)	26 (19.8%)	51 (19.0%)
		Moderate	12 (8.8%)	11 (8.4%)	23 (8.6%)
		Severe	14 (10.2%)	5 (3.8%)	19 (7.1%)
		Very Severe	2 (1.5%)	6 (4.6%)	8 (3.0%)
	Long Term Follow-up		N=15	N=9	N=24
		None	8 (53.3%)	4 (44.4%)	12 (50.0%)
		Mild	2 (13.3%)	1 (11.1%)	3 (12.5%)
		Moderate	4 (26.7%)	2 (22.2%)	6 (25.0%)
		Severe	1 (6.7%)	2 (22.2%)	3 (12.5%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea Frequency	Baseline		N=176	N=179	N=355
		Never	133 (75.6%)	125 (69.8%)	258 (72.7%)
		Rarely	22 (12.5%)	26 (14.5%)	48 (13.5%)
		Occasionally	17 (9.7%)	16 (8.9%)	33 (9.3%)
		Frequently	2 (1.1%)	8 (4.5%)	10 (2.8%)
		Almost Constantly	2 (1.1%)	4 (2.2%)	6 (1.7%)
	C2D1		N=163	N=150	N=313
		Never	73 (44.8%)	104 (69.3%)	177 (56.5%)
		Rarely	24 (14.7%)	27 (18.0%)	51 (16.3%)
		Occasionally	39 (23.9%)	17 (11.3%)	56 (17.9%)
		Frequently	19 (11.7%)	1 (0.7%)	20 (6.4%)
		Almost Constantly	8 (4.9%)	1 (0.7%)	9 (2.9%)
	C3D1		N=132	N=105	N=237
		Never	66 (50.0%)	68 (64.8%)	134 (56.5%)
		Rarely	21 (15.9%)	20 (19.0%)	41 (17.3%)
		Occasionally	21 (15.9%)	11 (10.5%)	32 (13.5%)
		Frequently	19 (14.4%)	6 (5.7%)	25 (10.5%)
		Almost Constantly	5 (3.8%)	0 (0.0%)	5 (2.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=118	N=97	N=215
		Never	48 (40.7%)	69 (71.1%)	117 (54.4%)
		Rarely	23 (19.5%)	14 (14.4%)	37 (17.2%)
		Occasionally	29 (24.6%)	12 (12.4%)	41 (19.1%)
		Frequently	14 (11.9%)	2 (2.1%)	16 (7.4%)
		Almost Constantly	4 (3.4%)	0 (0.0%)	4 (1.9%)
	C5D1		N=105	N=80	N=185
		Never	55 (52.4%)	53 (66.3%)	108 (58.4%)
		Rarely	11 (10.5%)	16 (20.0%)	27 (14.6%)
		Occasionally	22 (21.0%)	8 (10.0%)	30 (16.2%)
		Frequently	14 (13.3%)	3 (3.8%)	17 (9.2%)
		Almost Constantly	3 (2.9%)	0 (0.0%)	3 (1.6%)
	C6D1		N=102	N=74	N=176
		Never	48 (47.1%)	49 (66.2%)	97 (55.1%)
		Rarely	20 (19.6%)	12 (16.2%)	32 (18.2%)
		Occasionally	20 (19.6%)	10 (13.5%)	30 (17.0%)
		Frequently	8 (7.8%)	3 (4.1%)	11 (6.3%)
		Almost Constantly	6 (5.9%)	0 (0.0%)	6 (3.4%)
	C7D1		N=84	N=54	N=138
		Never	39 (46.4%)	39 (72.2%)	78 (56.5%)
		Rarely	24 (28.6%)	6 (11.1%)	30 (21.7%)
		Occasionally	16 (19.0%)	4 (7.4%)	20 (14.5%)
		Frequently	5 (6.0%)	5 (9.3%)	10 (7.2%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=80	N=50	N=130
		Never	38 (47.5%)	36 (72.0%)	74 (56.9%)
		Rarely	23 (28.8%)	7 (14.0%)	30 (23.1%)
		Occasionally	14 (17.5%)	5 (10.0%)	19 (14.6%)
		Frequently	3 (3.8%)	2 (4.0%)	5 (3.8%)
		Almost Constantly	2 (2.5%)	0 (0.0%)	2 (1.5%)
	C9D1		N=64	N=42	N=106
		Never	34 (53.1%)	30 (71.4%)	64 (60.4%)
		Rarely	14 (21.9%)	5 (11.9%)	19 (17.9%)
		Occasionally	9 (14.1%)	2 (4.8%)	11 (10.4%)
		Frequently	7 (10.9%)	4 (9.5%)	11 (10.4%)
		Almost Constantly	0 (0.0%)	1 (2.4%)	1 (0.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=57	N=31	N=88
		Never	31 (54.4%)	19 (61.3%)	50 (56.8%)
		Rarely	13 (22.8%)	5 (16.1%)	18 (20.5%)
		Occasionally	7 (12.3%)	3 (9.7%)	10 (11.4%)
		Frequently	5 (8.8%)	4 (12.9%)	9 (10.2%)
		Almost Constantly	1 (1.8%)	0 (0.0%)	1 (1.1%)
	C11D1		N=49	N=24	N=73
		Never	29 (59.2%)	16 (66.7%)	45 (61.6%)
		Rarely	11 (22.4%)	4 (16.7%)	15 (20.5%)
		Occasionally	5 (10.2%)	2 (8.3%)	7 (9.6%)
		Frequently	3 (6.1%)	2 (8.3%)	5 (6.8%)
		Almost Constantly	1 (2.0%)	0 (0.0%)	1 (1.4%)
	C12D1		N=43	N=20	N=63
		Never	23 (53.5%)	16 (80.0%)	39 (61.9%)
		Rarely	11 (25.6%)	1 (5.0%)	12 (19.0%)
		Occasionally	2 (4.7%)	1 (5.0%)	3 (4.8%)
		Frequently	6 (14.0%)	2 (10.0%)	8 (12.7%)
		Almost Constantly	1 (2.3%)	0 (0.0%)	1 (1.6%)
	C13D1		N=36	N=14	N=50
		Never	16 (44.4%)	11 (78.6%)	27 (54.0%)
		Rarely	8 (22.2%)	1 (7.1%)	9 (18.0%)
		Occasionally	8 (22.2%)	2 (14.3%)	10 (20.0%)
		Frequently	4 (11.1%)	0 (0.0%)	4 (8.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=35	N=13	N=48
		Never	13 (37.1%)	9 (69.2%)	22 (45.8%)
		Rarely	10 (28.6%)	2 (15.4%)	12 (25.0%)
		Occasionally	9 (25.7%)	2 (15.4%)	11 (22.9%)
		Frequently	2 (5.7%)	0 (0.0%)	2 (4.2%)
		Almost Constantly	1 (2.9%)	0 (0.0%)	1 (2.1%)
	C15D1		N=30	N=13	N=43
		Never	14 (46.7%)	9 (69.2%)	23 (53.5%)
		Rarely	6 (20.0%)	2 (15.4%)	8 (18.6%)
		Occasionally	5 (16.7%)	1 (7.7%)	6 (14.0%)
		Frequently	5 (16.7%)	1 (7.7%)	6 (14.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=30	N=11	N=41
		Never	15 (50.0%)	6 (54.5%)	21 (51.2%)
		Rarely	6 (20.0%)	3 (27.3%)	9 (22.0%)
		Occasionally	3 (10.0%)	1 (9.1%)	4 (9.8%)
		Frequently	6 (20.0%)	1 (9.1%)	7 (17.1%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=28	N=7	N=35
		Never	14 (50.0%)	6 (85.7%)	20 (57.1%)
		Rarely	3 (10.7%)	0 (0.0%)	3 (8.6%)
		Occasionally	7 (25.0%)	1 (14.3%)	8 (22.9%)
		Frequently	4 (14.3%)	0 (0.0%)	4 (11.4%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Never	11 (47.8%)	5 (71.4%)	16 (53.3%)
		Rarely	7 (30.4%)	0 (0.0%)	7 (23.3%)
		Occasionally	3 (13.0%)	2 (28.6%)	5 (16.7%)
		Frequently	2 (8.7%)	0 (0.0%)	2 (6.7%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C19D1		N=21	N=6	N=27
		Never	11 (52.4%)	5 (83.3%)	16 (59.3%)
		Rarely	5 (23.8%)	0 (0.0%)	5 (18.5%)
		Occasionally	4 (19.0%)	1 (16.7%)	5 (18.5%)
		Frequently	1 (4.8%)	0 (0.0%)	1 (3.7%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		Never	12 (60.0%)	2 (50.0%)	14 (58.3%)
		Rarely	2 (10.0%)	2 (50.0%)	4 (16.7%)
		Occasionally	3 (15.0%)	0 (0.0%)	3 (12.5%)
		Frequently	2 (10.0%)	0 (0.0%)	2 (8.3%)
		Almost Constantly	1 (5.0%)	0 (0.0%)	1 (4.2%)
	C21D1		N=18	N=4	N=22
		Never	10 (55.6%)	3 (75.0%)	13 (59.1%)
		Rarely	2 (11.1%)	1 (25.0%)	3 (13.6%)
		Occasionally	4 (22.2%)	0 (0.0%)	4 (18.2%)
		Frequently	1 (5.6%)	0 (0.0%)	1 (4.5%)
		Almost Constantly	1 (5.6%)	0 (0.0%)	1 (4.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=15	N=3	N=18
		Never	7 (46.7%)	1 (33.3%)	8 (44.4%)
		Rarely	3 (20.0%)	1 (33.3%)	4 (22.2%)
		Occasionally	5 (33.3%)	1 (33.3%)	6 (33.3%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Never	4 (40.0%)	1 (33.3%)	5 (38.5%)
		Rarely	3 (30.0%)	1 (33.3%)	4 (30.8%)
		Occasionally	3 (30.0%)	1 (33.3%)	4 (30.8%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		Never	6 (60.0%)	0 (0.0%)	6 (50.0%)
		Rarely	1 (10.0%)	1 (50.0%)	2 (16.7%)
		Occasionally	3 (30.0%)	1 (50.0%)	4 (33.3%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=9	N=0	N=9
		Never	5 (55.6%)	0 (NE)	5 (55.6%)
		Rarely	1 (11.1%)	0 (NE)	1 (11.1%)
		Occasionally	3 (33.3%)	0 (NE)	3 (33.3%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Never	3 (37.5%)	1 (100.0%)	4 (44.4%)
		Rarely	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Occasionally	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	1 (12.5%)	0 (0.0%)	1 (11.1%)
	C27D1		N=8	N=1	N=9
		Never	4 (50.0%)	1 (100.0%)	5 (55.6%)
		Rarely	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Occasionally	3 (37.5%)	0 (0.0%)	3 (33.3%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=7	N=1	N=8
		Never	3 (42.9%)	1 (100.0%)	4 (50.0%)
		Rarely	2 (28.6%)	0 (0.0%)	2 (25.0%)
		Occasionally	2 (28.6%)	0 (0.0%)	2 (25.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Never	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Rarely	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Almost Constantly	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Never	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Rarely	3 (75.0%)	1 (100.0%)	4 (80.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Never	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Rarely	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Never	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Rarely	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Never	2 (66.7%)	0 (0.0%)	2 (50.0%)
		Rarely	1 (33.3%)	1 (100.0%)	2 (50.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=3	N=0	N=3
		Never	1 (33.3%)	0 (NE)	1 (33.3%)
		Rarely	2 (66.7%)	0 (NE)	2 (66.7%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Never	2 (66.7%)	0 (NE)	2 (66.7%)
		Rarely	1 (33.3%)	0 (NE)	1 (33.3%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Never	2 (66.7%)	0 (NE)	2 (66.7%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	1 (33.3%)	0 (NE)	1 (33.3%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Never	1 (50.0%)	0 (NE)	1 (50.0%)
		Rarely	1 (50.0%)	0 (NE)	1 (50.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Never	1 (50.0%)	0 (NE)	1 (50.0%)
		Rarely	1 (50.0%)	0 (NE)	1 (50.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=137	N=130	N=267
		Never	81 (59.1%)	87 (66.9%)	168 (62.9%)
		Rarely	18 (13.1%)	24 (18.5%)	42 (15.7%)
		Occasionally	20 (14.6%)	15 (11.5%)	35 (13.1%)
		Frequently	13 (9.5%)	4 (3.1%)	17 (6.4%)
		Almost Constantly	5 (3.6%)	0 (0.0%)	5 (1.9%)
	Long Term		N=15	N=9	N=24
	Follow-up	Never	9 (60.0%)	2 (22.2%)	11 (45.8%)
		Rarely	2 (13.3%)	4 (44.4%)	6 (25.0%)
		Occasionally	3 (20.0%)	1 (11.1%)	4 (16.7%)
		Frequently	1 (6.7%)	0 (0.0%)	1 (4.2%)
		Almost Constantly	0 (0.0%)	2 (22.2%)	2 (8.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Abdominal Pain Frequency	Baseline		N=177	N=180	N=357
		Never	95 (53.7%)	94 (52.2%)	189 (52.9%)
		Rarely	38 (21.5%)	33 (18.3%)	71 (19.9%)
		Occasionally	26 (14.7%)	38 (21.1%)	64 (17.9%)
		Frequently	13 (7.3%)	10 (5.6%)	23 (6.4%)
		Almost Constantly	5 (2.8%)	5 (2.8%)	10 (2.8%)
	C2D1		N=162	N=151	N=313
		Never	74 (45.7%)	70 (46.4%)	144 (46.0%)
		Rarely	35 (21.6%)	32 (21.2%)	67 (21.4%)
		Occasionally	35 (21.6%)	36 (23.8%)	71 (22.7%)
		Frequently	16 (9.9%)	12 (7.9%)	28 (8.9%)
		Almost Constantly	2 (1.2%)	1 (0.7%)	3 (1.0%)
	C3D1		N=132	N=106	N=238
		Never	70 (53.0%)	49 (46.2%)	119 (50.0%)
		Rarely	29 (22.0%)	26 (24.5%)	55 (23.1%)
		Occasionally	25 (18.9%)	21 (19.8%)	46 (19.3%)
		Frequently	8 (6.1%)	9 (8.5%)	17 (7.1%)
		Almost Constantly	0 (0.0%)	1 (0.9%)	1 (0.4%)
	C4D1		N=118	N=97	N=215
		Never	63 (53.4%)	53 (54.6%)	116 (54.0%)
		Rarely	29 (24.6%)	22 (22.7%)	51 (23.7%)
		Occasionally	22 (18.6%)	15 (15.5%)	37 (17.2%)
		Frequently	4 (3.4%)	5 (5.2%)	9 (4.2%)
		Almost Constantly	0 (0.0%)	2 (2.1%)	2 (0.9%)
	C5D1		N=105	N=82	N=187
		Never	49 (46.7%)	38 (46.3%)	87 (46.5%)
		Rarely	30 (28.6%)	20 (24.4%)	50 (26.7%)
		Occasionally	18 (17.1%)	19 (23.2%)	37 (19.8%)
		Frequently	8 (7.6%)	4 (4.9%)	12 (6.4%)
		Almost Constantly	0 (0.0%)	1 (1.2%)	1 (0.5%)
	C6D1		N=102	N=73	N=175
		Never	54 (52.9%)	39 (53.4%)	93 (53.1%)
		Rarely	30 (29.4%)	18 (24.7%)	48 (27.4%)
		Occasionally	13 (12.7%)	11 (15.1%)	24 (13.7%)
		Frequently	4 (3.9%)	5 (6.8%)	9 (5.1%)
		Almost Constantly	1 (1.0%)	0 (0.0%)	1 (0.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=85	N=56	N=141
		Never	52 (61.2%)	37 (66.1%)	89 (63.1%)
		Rarely	17 (20.0%)	9 (16.1%)	26 (18.4%)
		Occasionally	11 (12.9%)	5 (8.9%)	16 (11.3%)
		Frequently	5 (5.9%)	4 (7.1%)	9 (6.4%)
		Almost Constantly	0 (0.0%)	1 (1.8%)	1 (0.7%)
	C8D1		N=79	N=51	N=130
		Never	43 (54.4%)	33 (64.7%)	76 (58.5%)
		Rarely	18 (22.8%)	8 (15.7%)	26 (20.0%)
		Occasionally	15 (19.0%)	8 (15.7%)	23 (17.7%)
		Frequently	2 (2.5%)	2 (3.9%)	4 (3.1%)
		Almost Constantly	1 (1.3%)	0 (0.0%)	1 (0.8%)
	C9D1		N=64	N=42	N=106
		Never	33 (51.6%)	27 (64.3%)	60 (56.6%)
		Rarely	20 (31.3%)	8 (19.0%)	28 (26.4%)
		Occasionally	9 (14.1%)	5 (11.9%)	14 (13.2%)
		Frequently	2 (3.1%)	2 (4.8%)	4 (3.8%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C10D1		N=56	N=31	N=87
		Never	34 (60.7%)	17 (54.8%)	51 (58.6%)
		Rarely	10 (17.9%)	6 (19.4%)	16 (18.4%)
		Occasionally	8 (14.3%)	6 (19.4%)	14 (16.1%)
		Frequently	3 (5.4%)	2 (6.5%)	5 (5.7%)
		Almost Constantly	1 (1.8%)	0 (0.0%)	1 (1.1%)
	C11D1		N=48	N=24	N=72
		Never	29 (60.4%)	13 (54.2%)	42 (58.3%)
		Rarely	12 (25.0%)	5 (20.8%)	17 (23.6%)
		Occasionally	5 (10.4%)	6 (25.0%)	11 (15.3%)
		Frequently	2 (4.2%)	0 (0.0%)	2 (2.8%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=43	N=20	N=63
		Never	28 (65.1%)	12 (60.0%)	40 (63.5%)
		Rarely	6 (14.0%)	6 (30.0%)	12 (19.0%)
		Occasionally	7 (16.3%)	1 (5.0%)	8 (12.7%)
		Frequently	2 (4.7%)	1 (5.0%)	3 (4.8%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=36	N=15	N=51
		Never	21 (58.3%)	9 (60.0%)	30 (58.8%)
		Rarely	8 (22.2%)	2 (13.3%)	10 (19.6%)
		Occasionally	7 (19.4%)	3 (20.0%)	10 (19.6%)
		Frequently	0 (0.0%)	1 (6.7%)	1 (2.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=35	N=13	N=48
		Never	22 (62.9%)	4 (30.8%)	26 (54.2%)
		Rarely	5 (14.3%)	4 (30.8%)	9 (18.8%)
		Occasionally	6 (17.1%)	3 (23.1%)	9 (18.8%)
		Frequently	2 (5.7%)	2 (15.4%)	4 (8.3%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=30	N=14	N=44
		Never	21 (70.0%)	7 (50.0%)	28 (63.6%)
		Rarely	5 (16.7%)	2 (14.3%)	7 (15.9%)
		Occasionally	4 (13.3%)	3 (21.4%)	7 (15.9%)
		Frequently	0 (0.0%)	2 (14.3%)	2 (4.5%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C16D1		N=30	N=11	N=41
		Never	20 (66.7%)	5 (45.5%)	25 (61.0%)
		Rarely	7 (23.3%)	2 (18.2%)	9 (22.0%)
		Occasionally	2 (6.7%)	3 (27.3%)	5 (12.2%)
		Frequently	1 (3.3%)	1 (9.1%)	2 (4.9%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=28	N=7	N=35
		Never	21 (75.0%)	2 (28.6%)	23 (65.7%)
		Rarely	2 (7.1%)	2 (28.6%)	4 (11.4%)
		Occasionally	3 (10.7%)	2 (28.6%)	5 (14.3%)
		Frequently	2 (7.1%)	1 (14.3%)	3 (8.6%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Never	16 (69.6%)	2 (28.6%)	18 (60.0%)
		Rarely	3 (13.0%)	1 (14.3%)	4 (13.3%)
		Occasionally	3 (13.0%)	2 (28.6%)	5 (16.7%)
		Frequently	1 (4.3%)	2 (28.6%)	3 (10.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=21	N=6	N=27
		Never	13 (61.9%)	2 (33.3%)	15 (55.6%)
		Rarely	4 (19.0%)	1 (16.7%)	5 (18.5%)
		Occasionally	2 (9.5%)	3 (50.0%)	5 (18.5%)
		Frequently	2 (9.5%)	0 (0.0%)	2 (7.4%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		Never	15 (75.0%)	1 (25.0%)	16 (66.7%)
		Rarely	3 (15.0%)	3 (75.0%)	6 (25.0%)
		Occasionally	1 (5.0%)	0 (0.0%)	1 (4.2%)
		Frequently	1 (5.0%)	0 (0.0%)	1 (4.2%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		Never	14 (77.8%)	1 (25.0%)	15 (68.2%)
		Rarely	4 (22.2%)	2 (50.0%)	6 (27.3%)
		Occasionally	0 (0.0%)	1 (25.0%)	1 (4.5%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C22D1		N=15	N=3	N=18
		Never	9 (60.0%)	1 (33.3%)	10 (55.6%)
		Rarely	4 (26.7%)	1 (33.3%)	5 (27.8%)
		Occasionally	2 (13.3%)	1 (33.3%)	3 (16.7%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Never	6 (60.0%)	1 (33.3%)	7 (53.8%)
		Rarely	3 (30.0%)	1 (33.3%)	4 (30.8%)
		Occasionally	1 (10.0%)	1 (33.3%)	2 (15.4%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		Never	7 (70.0%)	1 (50.0%)	8 (66.7%)
		Rarely	2 (20.0%)	0 (0.0%)	2 (16.7%)
		Occasionally	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Frequently	0 (0.0%)	1 (50.0%)	1 (8.3%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=9	N=0	N=9
		Never	5 (55.6%)	0 (NE)	5 (55.6%)
		Rarely	3 (33.3%)	0 (NE)	3 (33.3%)
		Occasionally	1 (11.1%)	0 (NE)	1 (11.1%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Never	4 (50.0%)	1 (100.0%)	5 (55.6%)
		Rarely	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Occasionally	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		Never	5 (62.5%)	1 (100.0%)	6 (66.7%)
		Rarely	3 (37.5%)	0 (0.0%)	3 (33.3%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		Never	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Rarely	2 (28.6%)	0 (0.0%)	2 (25.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Never	3 (75.0%)	0 (0.0%)	3 (60.0%)
		Rarely	0 (0.0%)	1 (100.0%)	1 (20.0%)
		Occasionally	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Never	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Rarely	2 (50.0%)	0 (0.0%)	2 (40.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		Never	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Never	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Never	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Rarely	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Frequently	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		Never	3 (100.0%)	0 (NE)	3 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Never	1 (50.0%)	0 (NE)	1 (50.0%)
		Rarely	1 (50.0%)	0 (NE)	1 (50.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Never	3 (100.0%)	0 (NE)	3 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=3	N=0	N=3
		Never	3 (100.0%)	0 (NE)	3 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Never	2 (100.0%)	0 (NE)	2 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		Never	1 (100.0%)	0 (NE)	1 (100.0%)
		Rarely	0 (0.0%)	0 (NE)	0 (0.0%)
		Occasionally	0 (0.0%)	0 (NE)	0 (0.0%)
		Frequently	0 (0.0%)	0 (NE)	0 (0.0%)
		Almost Constantly	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=134	N=132	N=266
		Never	67 (50.0%)	64 (48.5%)	131 (49.2%)
		Rarely	29 (21.6%)	32 (24.2%)	61 (22.9%)
		Occasionally	24 (17.9%)	19 (14.4%)	43 (16.2%)
		Frequently	11 (8.2%)	15 (11.4%)	26 (9.8%)
		Almost Constantly	3 (2.2%)	2 (1.5%)	5 (1.9%)
	Long Term		N=15	N=9	N=24
	Follow-up	Never	6 (40.0%)	4 (44.4%)	10 (41.7%)
		Rarely	6 (40.0%)	2 (22.2%)	8 (33.3%)
		Occasionally	3 (20.0%)	2 (22.2%)	5 (20.8%)
		Frequently	0 (0.0%)	1 (11.1%)	1 (4.2%)
		Almost Constantly	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abdominal Pain Severity	Baseline		N=174	N=177	N=351
		None	98 (56.3%)	96 (54.2%)	194 (55.3%)
		Mild	44 (25.3%)	49 (27.7%)	93 (26.5%)
		Moderate	22 (12.6%)	22 (12.4%)	44 (12.5%)
		Severe	8 (4.6%)	9 (5.1%)	17 (4.8%)
		Very Severe	2 (1.1%)	1 (0.6%)	3 (0.9%)
	C2D1		N=159	N=149	N=308
		None	72 (45.3%)	77 (51.7%)	149 (48.4%)
		Mild	47 (29.6%)	39 (26.2%)	86 (27.9%)
		Moderate	32 (20.1%)	27 (18.1%)	59 (19.2%)
		Severe	7 (4.4%)	6 (4.0%)	13 (4.2%)
		Very Severe	1 (0.6%)	0 (0.0%)	1 (0.3%)
	C3D1		N=130	N=103	N=233
		None	70 (53.8%)	49 (47.6%)	119 (51.1%)
		Mild	36 (27.7%)	31 (30.1%)	67 (28.8%)
		Moderate	24 (18.5%)	19 (18.4%)	43 (18.5%)
		Severe	0 (0.0%)	4 (3.9%)	4 (1.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=118	N=96	N=214
		None	66 (55.9%)	53 (55.2%)	119 (55.6%)
		Mild	30 (25.4%)	22 (22.9%)	52 (24.3%)
		Moderate	20 (16.9%)	18 (18.8%)	38 (17.8%)
		Severe	2 (1.7%)	3 (3.1%)	5 (2.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C5D1		N=101	N=79	N=180
		None	50 (49.5%)	37 (46.8%)	87 (48.3%)
		Mild	28 (27.7%)	30 (38.0%)	58 (32.2%)
		Moderate	21 (20.8%)	8 (10.1%)	29 (16.1%)
		Severe	2 (2.0%)	4 (5.1%)	6 (3.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C6D1		N=98	N=72	N=170
		None	55 (56.1%)	41 (56.9%)	96 (56.5%)
		Mild	28 (28.6%)	21 (29.2%)	49 (28.8%)
		Moderate	11 (11.2%)	9 (12.5%)	20 (11.8%)
		Severe	3 (3.1%)	1 (1.4%)	4 (2.4%)
		Very Severe	1 (1.0%)	0 (0.0%)	1 (0.6%)
	C7D1		N=81	N=52	N=133
		None	52 (64.2%)	35 (67.3%)	87 (65.4%)
		Mild	13 (16.0%)	7 (13.5%)	20 (15.0%)
		Moderate	15 (18.5%)	8 (15.4%)	23 (17.3%)
		Severe	1 (1.2%)	1 (1.9%)	2 (1.5%)
		Very Severe	0 (0.0%)	1 (1.9%)	1 (0.8%)
	C8D1		N=77	N=49	N=126
		None	43 (55.8%)	31 (63.3%)	74 (58.7%)
		Mild	19 (24.7%)	12 (24.5%)	31 (24.6%)
		Moderate	12 (15.6%)	5 (10.2%)	17 (13.5%)
		Severe	1 (1.3%)	1 (2.0%)	2 (1.6%)
		Very Severe	2 (2.6%)	0 (0.0%)	2 (1.6%)
	C9D1		N=61	N=41	N=102
		None	33 (54.1%)	27 (65.9%)	60 (58.8%)
		Mild	20 (32.8%)	8 (19.5%)	28 (27.5%)
		Moderate	8 (13.1%)	3 (7.3%)	11 (10.8%)
		Severe	0 (0.0%)	3 (7.3%)	3 (2.9%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=54	N=29	N=83
		None	34 (63.0%)	15 (51.7%)	49 (59.0%)
		Mild	11 (20.4%)	8 (27.6%)	19 (22.9%)
		Moderate	8 (14.8%)	4 (13.8%)	12 (14.5%)
		Severe	1 (1.9%)	2 (6.9%)	3 (3.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=48	N=23	N=71
		None	31 (64.6%)	12 (52.2%)	43 (60.6%)
		Mild	11 (22.9%)	8 (34.8%)	19 (26.8%)
		Moderate	6 (12.5%)	3 (13.0%)	9 (12.7%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=42	N=19	N=61
		None	29 (69.0%)	13 (68.4%)	42 (68.9%)
		Mild	6 (14.3%)	4 (21.1%)	10 (16.4%)
		Moderate	5 (11.9%)	2 (10.5%)	7 (11.5%)
		Severe	2 (4.8%)	0 (0.0%)	2 (3.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C13D1		N=32	N=14	N=46
		None	18 (56.3%)	9 (64.3%)	27 (58.7%)
		Mild	8 (25.0%)	2 (14.3%)	10 (21.7%)
		Moderate	5 (15.6%)	3 (21.4%)	8 (17.4%)
		Severe	1 (3.1%)	0 (0.0%)	1 (2.2%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=34	N=13	N=47
		None	22 (64.7%)	4 (30.8%)	26 (55.3%)
		Mild	5 (14.7%)	6 (46.2%)	11 (23.4%)
		Moderate	6 (17.6%)	2 (15.4%)	8 (17.0%)
		Severe	1 (2.9%)	1 (7.7%)	2 (4.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=29	N=13	N=42
		None	20 (69.0%)	6 (46.2%)	26 (61.9%)
		Mild	7 (24.1%)	3 (23.1%)	10 (23.8%)
		Moderate	1 (3.4%)	2 (15.4%)	3 (7.1%)
		Severe	1 (3.4%)	2 (15.4%)	3 (7.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=28	N=11	N=39
		None	19 (67.9%)	5 (45.5%)	24 (61.5%)
		Mild	7 (25.0%)	2 (18.2%)	9 (23.1%)
		Moderate	2 (7.1%)	3 (27.3%)	5 (12.8%)
		Severe	0 (0.0%)	1 (9.1%)	1 (2.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=27	N=7	N=34
		None	20 (74.1%)	2 (28.6%)	22 (64.7%)
		Mild	3 (11.1%)	1 (14.3%)	4 (11.8%)
		Moderate	4 (14.8%)	4 (57.1%)	8 (23.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		None	16 (69.6%)	2 (28.6%)	18 (60.0%)
		Mild	3 (13.0%)	1 (14.3%)	4 (13.3%)
		Moderate	3 (13.0%)	4 (57.1%)	7 (23.3%)
		Severe	1 (4.3%)	0 (0.0%)	1 (3.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C19D1		N=21	N=5	N=26
		None	13 (61.9%)	1 (20.0%)	14 (53.8%)
		Mild	5 (23.8%)	3 (60.0%)	8 (30.8%)
		Moderate	2 (9.5%)	1 (20.0%)	3 (11.5%)
		Severe	1 (4.8%)	0 (0.0%)	1 (3.8%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=19	N=4	N=23
		None	15 (78.9%)	1 (25.0%)	16 (69.6%)
		Mild	2 (10.5%)	2 (50.0%)	4 (17.4%)
		Moderate	2 (10.5%)	1 (25.0%)	3 (13.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		None	15 (83.3%)	1 (25.0%)	16 (72.7%)
		Mild	3 (16.7%)	2 (50.0%)	5 (22.7%)
		Moderate	0 (0.0%)	1 (25.0%)	1 (4.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=14	N=3	N=17
		None	9 (64.3%)	1 (33.3%)	10 (58.8%)
		Mild	2 (14.3%)	1 (33.3%)	3 (17.6%)
		Moderate	3 (21.4%)	1 (33.3%)	4 (23.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		None	6 (60.0%)	1 (33.3%)	7 (53.8%)
		Mild	3 (30.0%)	1 (33.3%)	4 (30.8%)
		Moderate	1 (10.0%)	1 (33.3%)	2 (15.4%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		None	7 (70.0%)	1 (50.0%)	8 (66.7%)
		Mild	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Moderate	2 (20.0%)	1 (50.0%)	3 (25.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=8	N=0	N=8
		None	4 (50.0%)	0 (NE)	4 (50.0%)
		Mild	3 (37.5%)	0 (NE)	3 (37.5%)
		Moderate	1 (12.5%)	0 (NE)	1 (12.5%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		None	4 (50.0%)	1 (100.0%)	5 (55.6%)
		Mild	3 (37.5%)	0 (0.0%)	3 (33.3%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		None	5 (62.5%)	1 (100.0%)	6 (66.7%)
		Mild	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Moderate	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=7	N=1	N=8
		None	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Mild	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Moderate	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		None	3 (75.0%)	0 (0.0%)	3 (60.0%)
		Mild	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		None	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Mild	2 (50.0%)	0 (0.0%)	2 (40.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		None	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		None	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		None	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		None	1 (50.0%)	0 (NE)	1 (50.0%)
		Mild	1 (50.0%)	0 (NE)	1 (50.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=128	N=127	N=255
		None	64 (50.0%)	66 (52.0%)	130 (51.0%)
		Mild	32 (25.0%)	33 (26.0%)	65 (25.5%)
		Moderate	21 (16.4%)	21 (16.5%)	42 (16.5%)
		Severe	10 (7.8%)	6 (4.7%)	16 (6.3%)
		Very Severe	1 (0.8%)	1 (0.8%)	2 (0.8%)
	Long Term		N=15	N=9	N=24
	Follow-up	None	8 (53.3%)	4 (44.4%)	12 (50.0%)
		Mild	5 (33.3%)	3 (33.3%)	8 (33.3%)
		Moderate	2 (13.3%)	0 (0.0%)	2 (8.3%)
		Severe	0 (0.0%)	1 (11.1%)	1 (4.2%)
		Very Severe	0 (0.0%)	1 (11.1%)	1 (4.2%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Abdominal Pain Interference	Baseline		N=173	N=176	N=349
		Not At All	126 (72.8%)	127 (72.2%)	253 (72.5%)
		A Little Bit	24 (13.9%)	36 (20.5%)	60 (17.2%)
		Somewhat	13 (7.5%)	8 (4.5%)	21 (6.0%)
		Quite A Bit	7 (4.0%)	3 (1.7%)	10 (2.9%)
		Very Much	3 (1.7%)	2 (1.1%)	5 (1.4%)
	C2D1		N=157	N=144	N=301
		Not At All	102 (65.0%)	104 (72.2%)	206 (68.4%)
		A Little Bit	35 (22.3%)	24 (16.7%)	59 (19.6%)
		Somewhat	12 (7.6%)	11 (7.6%)	23 (7.6%)
		Quite A Bit	7 (4.5%)	5 (3.5%)	12 (4.0%)
		Very Much	1 (0.6%)	0 (0.0%)	1 (0.3%)
	C3D1		N=131	N=104	N=235
		Not At All	98 (74.8%)	74 (71.2%)	172 (73.2%)
		A Little Bit	26 (19.8%)	20 (19.2%)	46 (19.6%)
		Somewhat	6 (4.6%)	9 (8.7%)	15 (6.4%)
		Quite A Bit	1 (0.8%)	1 (1.0%)	2 (0.9%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C4D1		N=115	N=95	N=210
		Not At All	88 (76.5%)	68 (71.6%)	156 (74.3%)
		A Little Bit	18 (15.7%)	19 (20.0%)	37 (17.6%)
		Somewhat	7 (6.1%)	6 (6.3%)	13 (6.2%)
		Quite A Bit	1 (0.9%)	2 (2.1%)	3 (1.4%)
		Very Much	1 (0.9%)	0 (0.0%)	1 (0.5%)
	C5D1		N=102	N=79	N=181
		Not At All	74 (72.5%)	56 (70.9%)	130 (71.8%)
		A Little Bit	16 (15.7%)	14 (17.7%)	30 (16.6%)
		Somewhat	8 (7.8%)	7 (8.9%)	15 (8.3%)
		Quite A Bit	3 (2.9%)	2 (2.5%)	5 (2.8%)
		Very Much	1 (1.0%)	0 (0.0%)	1 (0.6%)
	C6D1		N=97	N=72	N=169
		Not At All	72 (74.2%)	55 (76.4%)	127 (75.1%)
		A Little Bit	16 (16.5%)	12 (16.7%)	28 (16.6%)
		Somewhat	6 (6.2%)	4 (5.6%)	10 (5.9%)
		Quite A Bit	2 (2.1%)	1 (1.4%)	3 (1.8%)
		Very Much	1 (1.0%)	0 (0.0%)	1 (0.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=81	N=52	N=133
		Not At All	63 (77.8%)	40 (76.9%)	103 (77.4%)
		A Little Bit	10 (12.3%)	6 (11.5%)	16 (12.0%)
		Somewhat	6 (7.4%)	5 (9.6%)	11 (8.3%)
		Quite A Bit	1 (1.2%)	0 (0.0%)	1 (0.8%)
		Very Much	1 (1.2%)	1 (1.9%)	2 (1.5%)
	C8D1		N=78	N=48	N=126
		Not At All	57 (73.1%)	40 (83.3%)	97 (77.0%)
		A Little Bit	13 (16.7%)	6 (12.5%)	19 (15.1%)
		Somewhat	3 (3.8%)	1 (2.1%)	4 (3.2%)
		Quite A Bit	3 (3.8%)	1 (2.1%)	4 (3.2%)
		Very Much	2 (2.6%)	0 (0.0%)	2 (1.6%)
	C9D1		N=58	N=41	N=99
		Not At All	43 (74.1%)	32 (78.0%)	75 (75.8%)
		A Little Bit	13 (22.4%)	5 (12.2%)	18 (18.2%)
		Somewhat	2 (3.4%)	2 (4.9%)	4 (4.0%)
		Quite A Bit	0 (0.0%)	2 (4.9%)	2 (2.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C10D1		N=53	N=29	N=82
		Not At All	41 (77.4%)	22 (75.9%)	63 (76.8%)
		A Little Bit	7 (13.2%)	3 (10.3%)	10 (12.2%)
		Somewhat	3 (5.7%)	2 (6.9%)	5 (6.1%)
		Quite A Bit	2 (3.8%)	2 (6.9%)	4 (4.9%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C11D1		N=48	N=23	N=71
		Not At All	39 (81.3%)	18 (78.3%)	57 (80.3%)
		A Little Bit	6 (12.5%)	3 (13.0%)	9 (12.7%)
		Somewhat	3 (6.3%)	2 (8.7%)	5 (7.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=41	N=19	N=60
		Not At All	32 (78.0%)	17 (89.5%)	49 (81.7%)
		A Little Bit	5 (12.2%)	1 (5.3%)	6 (10.0%)
		Somewhat	3 (7.3%)	1 (5.3%)	4 (6.7%)
		Quite A Bit	1 (2.4%)	0 (0.0%)	1 (1.7%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=32	N=14	N=46
		Not At All	22 (68.8%)	10 (71.4%)	32 (69.6%)
		A Little Bit	9 (28.1%)	3 (21.4%)	12 (26.1%)
		Somewhat	1 (3.1%)	1 (7.1%)	2 (4.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=33	N=13	N=46
		Not At All	26 (78.8%)	8 (61.5%)	34 (73.9%)
		A Little Bit	4 (12.1%)	3 (23.1%)	7 (15.2%)
		Somewhat	2 (6.1%)	2 (15.4%)	4 (8.7%)
		Quite A Bit	1 (3.0%)	0 (0.0%)	1 (2.2%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=28	N=12	N=40
		Not At All	22 (78.6%)	6 (50.0%)	28 (70.0%)
		A Little Bit	4 (14.3%)	4 (33.3%)	8 (20.0%)
		Somewhat	1 (3.6%)	2 (16.7%)	3 (7.5%)
		Quite A Bit	1 (3.6%)	0 (0.0%)	1 (2.5%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C16D1		N=28	N=11	N=39
		Not At All	25 (89.3%)	5 (45.5%)	30 (76.9%)
		A Little Bit	2 (7.1%)	4 (36.4%)	6 (15.4%)
		Somewhat	1 (3.6%)	2 (18.2%)	3 (7.7%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=27	N=6	N=33
		Not At All	20 (74.1%)	3 (50.0%)	23 (69.7%)
		A Little Bit	4 (14.8%)	1 (16.7%)	5 (15.2%)
		Somewhat	3 (11.1%)	2 (33.3%)	5 (15.2%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Not At All	17 (73.9%)	3 (42.9%)	20 (66.7%)
		A Little Bit	4 (17.4%)	0 (0.0%)	4 (13.3%)
		Somewhat	1 (4.3%)	4 (57.1%)	5 (16.7%)
		Quite A Bit	1 (4.3%)	0 (0.0%)	1 (3.3%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=20	N=5	N=25
		Not At All	16 (80.0%)	2 (40.0%)	18 (72.0%)
		A Little Bit	1 (5.0%)	3 (60.0%)	4 (16.0%)
		Somewhat	2 (10.0%)	0 (0.0%)	2 (8.0%)
		Quite A Bit	1 (5.0%)	0 (0.0%)	1 (4.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=19	N=4	N=23
		Not At All	17 (89.5%)	3 (75.0%)	20 (87.0%)
		A Little Bit	1 (5.3%)	1 (25.0%)	2 (8.7%)
		Somewhat	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		Not At All	17 (94.4%)	2 (50.0%)	19 (86.4%)
		A Little Bit	1 (5.6%)	2 (50.0%)	3 (13.6%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C22D1		N=14	N=3	N=17
		Not At All	10 (71.4%)	1 (33.3%)	11 (64.7%)
		A Little Bit	2 (14.3%)	2 (66.7%)	4 (23.5%)
		Somewhat	2 (14.3%)	0 (0.0%)	2 (11.8%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Not At All	9 (90.0%)	2 (66.7%)	11 (84.6%)
		A Little Bit	1 (10.0%)	1 (33.3%)	2 (15.4%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		Not At All	8 (80.0%)	1 (50.0%)	9 (75.0%)
		A Little Bit	2 (20.0%)	0 (0.0%)	2 (16.7%)
		Somewhat	0 (0.0%)	1 (50.0%)	1 (8.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=8	N=0	N=8
		Not At All	5 (62.5%)	0 (NE)	5 (62.5%)
		A Little Bit	2 (25.0%)	0 (NE)	2 (25.0%)
		Somewhat	1 (12.5%)	0 (NE)	1 (12.5%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Not At All	5 (62.5%)	1 (100.0%)	6 (66.7%)
		A Little Bit	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Somewhat	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Quite A Bit	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		Not At All	6 (75.0%)	1 (100.0%)	7 (77.8%)
		A Little Bit	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		Not At All	6 (85.7%)	1 (100.0%)	7 (87.5%)
		A Little Bit	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Not At All	3 (75.0%)	0 (0.0%)	3 (60.0%)
		A Little Bit	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Not At All	3 (75.0%)	1 (100.0%)	4 (80.0%)
		A Little Bit	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
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Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		Not At All	2 (100.0%)	1 (100.0%)	3 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Not At All	2 (100.0%)	1 (100.0%)	3 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Not At All	3 (100.0%)	1 (100.0%)	4 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=125	N=122	N=247
		Not At All	83 (66.4%)	79 (64.8%)	162 (65.6%)
		A Little Bit	18 (14.4%)	26 (21.3%)	44 (17.8%)
		Somewhat	15 (12.0%)	8 (6.6%)	23 (9.3%)
		Quite A Bit	6 (4.8%)	7 (5.7%)	13 (5.3%)
		Very Much	3 (2.4%)	2 (1.6%)	5 (2.0%)
	Long Term		N=15	N=9	N=24
	Follow-up	Not At All	12 (80.0%)	5 (55.6%)	17 (70.8%)
		A Little Bit	1 (6.7%)	2 (22.2%)	3 (12.5%)
		Somewhat	1 (6.7%)	0 (0.0%)	1 (4.2%)
		Quite A Bit	1 (6.7%)	2 (22.2%)	3 (12.5%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
Shortness of Breath Severity	Baseline		N=177	N=179	N=356
		None	92 (52.0%)	90 (50.3%)	182 (51.1%)
		Mild	54 (30.5%)	51 (28.5%)	105 (29.5%)
		Moderate	20 (11.3%)	21 (11.7%)	41 (11.5%)
		Severe	8 (4.5%)	13 (7.3%)	21 (5.9%)
		Very Severe	3 (1.7%)	4 (2.2%)	7 (2.0%)
	C2D1		N=161	N=151	N=312
		None	89 (55.3%)	70 (46.4%)	159 (51.0%)
		Mild	44 (27.3%)	40 (26.5%)	84 (26.9%)
		Moderate	18 (11.2%)	28 (18.5%)	46 (14.7%)
		Severe	10 (6.2%)	10 (6.6%)	20 (6.4%)
		Very Severe	0 (0.0%)	3 (2.0%)	3 (1.0%)
	C3D1		N=132	N=106	N=238
		None	78 (59.1%)	49 (46.2%)	127 (53.4%)
		Mild	33 (25.0%)	30 (28.3%)	63 (26.5%)
		Moderate	16 (12.1%)	20 (18.9%)	36 (15.1%)
		Severe	5 (3.8%)	6 (5.7%)	11 (4.6%)
		Very Severe	0 (0.0%)	1 (0.9%)	1 (0.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=116	N=97	N=213
		None	67 (57.8%)	40 (41.2%)	107 (50.2%)
		Mild	29 (25.0%)	33 (34.0%)	62 (29.1%)
		Moderate	14 (12.1%)	20 (20.6%)	34 (16.0%)
		Severe	4 (3.4%)	4 (4.1%)	8 (3.8%)
		Very Severe	2 (1.7%)	0 (0.0%)	2 (0.9%)
	C5D1		N=105	N=82	N=187
		None	60 (57.1%)	42 (51.2%)	102 (54.5%)
		Mild	24 (22.9%)	19 (23.2%)	43 (23.0%)
		Moderate	18 (17.1%)	17 (20.7%)	35 (18.7%)
		Severe	3 (2.9%)	4 (4.9%)	7 (3.7%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C6D1		N=100	N=73	N=173
		None	65 (65.0%)	38 (52.1%)	103 (59.5%)
		Mild	23 (23.0%)	21 (28.8%)	44 (25.4%)
		Moderate	11 (11.0%)	11 (15.1%)	22 (12.7%)
		Severe	1 (1.0%)	2 (2.7%)	3 (1.7%)
		Very Severe	0 (0.0%)	1 (1.4%)	1 (0.6%)
	C7D1		N=85	N=56	N=141
		None	53 (62.4%)	31 (55.4%)	84 (59.6%)
		Mild	20 (23.5%)	16 (28.6%)	36 (25.5%)
		Moderate	9 (10.6%)	8 (14.3%)	17 (12.1%)
		Severe	3 (3.5%)	1 (1.8%)	4 (2.8%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=80	N=51	N=131
		None	52 (65.0%)	28 (54.9%)	80 (61.1%)
		Mild	13 (16.3%)	14 (27.5%)	27 (20.6%)
		Moderate	13 (16.3%)	5 (9.8%)	18 (13.7%)
		Severe	1 (1.3%)	4 (7.8%)	5 (3.8%)
		Very Severe	1 (1.3%)	0 (0.0%)	1 (0.8%)
	C9D1		N=64	N=42	N=106
		None	40 (62.5%)	25 (59.5%)	65 (61.3%)
		Mild	19 (29.7%)	10 (23.8%)	29 (27.4%)
		Moderate	3 (4.7%)	5 (11.9%)	8 (7.5%)
		Severe	2 (3.1%)	2 (4.8%)	4 (3.8%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=56	N=31	N=87
		None	37 (66.1%)	16 (51.6%)	53 (60.9%)
		Mild	14 (25.0%)	11 (35.5%)	25 (28.7%)
		Moderate	3 (5.4%)	2 (6.5%)	5 (5.7%)
		Severe	1 (1.8%)	2 (6.5%)	3 (3.4%)
		Very Severe	1 (1.8%)	0 (0.0%)	1 (1.1%)
	C11D1		N=49	N=24	N=73
		None	26 (53.1%)	12 (50.0%)	38 (52.1%)
		Mild	18 (36.7%)	9 (37.5%)	27 (37.0%)
		Moderate	5 (10.2%)	3 (12.5%)	8 (11.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=43	N=20	N=63
		None	26 (60.5%)	9 (45.0%)	35 (55.6%)
		Mild	12 (27.9%)	10 (50.0%)	22 (34.9%)
		Moderate	4 (9.3%)	1 (5.0%)	5 (7.9%)
		Severe	1 (2.3%)	0 (0.0%)	1 (1.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C13D1		N=36	N=15	N=51
		None	20 (55.6%)	6 (40.0%)	26 (51.0%)
		Mild	10 (27.8%)	8 (53.3%)	18 (35.3%)
		Moderate	5 (13.9%)	1 (6.7%)	6 (11.8%)
		Severe	1 (2.8%)	0 (0.0%)	1 (2.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C14D1		N=35	N=13	N=48
		None	20 (57.1%)	8 (61.5%)	28 (58.3%)
		Mild	11 (31.4%)	4 (30.8%)	15 (31.3%)
		Moderate	4 (11.4%)	1 (7.7%)	5 (10.4%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=30	N=14	N=44
		None	17 (56.7%)	4 (28.6%)	21 (47.7%)
		Mild	8 (26.7%)	7 (50.0%)	15 (34.1%)
		Moderate	4 (13.3%)	2 (14.3%)	6 (13.6%)
		Severe	1 (3.3%)	1 (7.1%)	2 (4.5%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=30	N=11	N=41
		None	17 (56.7%)	4 (36.4%)	21 (51.2%)
		Mild	9 (30.0%)	5 (45.5%)	14 (34.1%)
		Moderate	4 (13.3%)	2 (18.2%)	6 (14.6%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=28	N=7	N=35
		None	16 (57.1%)	4 (57.1%)	20 (57.1%)
		Mild	8 (28.6%)	1 (14.3%)	9 (25.7%)
		Moderate	4 (14.3%)	2 (28.6%)	6 (17.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		None	13 (56.5%)	3 (42.9%)	16 (53.3%)
		Mild	8 (34.8%)	2 (28.6%)	10 (33.3%)
		Moderate	2 (8.7%)	2 (28.6%)	4 (13.3%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C19D1		N=21	N=6	N=27
		None	10 (47.6%)	1 (16.7%)	11 (40.7%)
		Mild	10 (47.6%)	4 (66.7%)	14 (51.9%)
		Moderate	1 (4.8%)	1 (16.7%)	2 (7.4%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		None	10 (50.0%)	2 (50.0%)	12 (50.0%)
		Mild	9 (45.0%)	0 (0.0%)	9 (37.5%)
		Moderate	1 (5.0%)	2 (50.0%)	3 (12.5%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		None	9 (50.0%)	2 (50.0%)	11 (50.0%)
		Mild	8 (44.4%)	0 (0.0%)	8 (36.4%)
		Moderate	1 (5.6%)	2 (50.0%)	3 (13.6%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=15	N=3	N=18
		None	7 (46.7%)	1 (33.3%)	8 (44.4%)
		Mild	7 (46.7%)	0 (0.0%)	7 (38.9%)
		Moderate	1 (6.7%)	2 (66.7%)	3 (16.7%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		None	5 (50.0%)	1 (33.3%)	6 (46.2%)
		Mild	5 (50.0%)	1 (33.3%)	6 (46.2%)
		Moderate	0 (0.0%)	1 (33.3%)	1 (7.7%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		None	5 (50.0%)	1 (50.0%)	6 (50.0%)
		Mild	5 (50.0%)	0 (0.0%)	5 (41.7%)
		Moderate	0 (0.0%)	1 (50.0%)	1 (8.3%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=9	N=0	N=9
		None	5 (55.6%)	0 (NE)	5 (55.6%)
		Mild	4 (44.4%)	0 (NE)	4 (44.4%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		None	4 (50.0%)	1 (100.0%)	5 (55.6%)
		Mild	4 (50.0%)	0 (0.0%)	4 (44.4%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		None	4 (50.0%)	1 (100.0%)	5 (55.6%)
		Mild	3 (37.5%)	0 (0.0%)	3 (33.3%)
		Moderate	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=7	N=1	N=8
		None	3 (42.9%)	1 (100.0%)	4 (50.0%)
		Mild	4 (57.1%)	0 (0.0%)	4 (50.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		None	3 (75.0%)	1 (100.0%)	4 (80.0%)
		Mild	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Moderate	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		None	3 (75.0%)	0 (0.0%)	3 (60.0%)
		Mild	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		None	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Mild	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		None	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Mild	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		None	3 (100.0%)	0 (0.0%)	3 (75.0%)
		Mild	0 (0.0%)	1 (100.0%)	1 (25.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		None	1 (50.0%)	0 (NE)	1 (50.0%)
		Mild	1 (50.0%)	0 (NE)	1 (50.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=135	N=131	N=266
		None	64 (47.4%)	63 (48.1%)	127 (47.7%)
		Mild	43 (31.9%)	40 (30.5%)	83 (31.2%)
		Moderate	15 (11.1%)	14 (10.7%)	29 (10.9%)
		Severe	9 (6.7%)	11 (8.4%)	20 (7.5%)
		Very Severe	4 (3.0%)	3 (2.3%)	7 (2.6%)
	Long Term		N=15	N=9	N=24
	Follow-up	None	8 (53.3%)	3 (33.3%)	11 (45.8%)
		Mild	5 (33.3%)	4 (44.4%)	9 (37.5%)
		Moderate	2 (13.3%)	0 (0.0%)	2 (8.3%)
		Severe	0 (0.0%)	2 (22.2%)	2 (8.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Shortness of Breath	Baseline		N=174	N=178	N=352
Interference		Not At All	109 (62.6%)	106 (59.6%)	215 (61.1%)
		A Little Bit	42 (24.1%)	38 (21.3%)	80 (22.7%)
		Somewhat	13 (7.5%)	17 (9.6%)	30 (8.5%)
		Quite A Bit	5 (2.9%)	13 (7.3%)	18 (5.1%)
		Very Much	5 (2.9%)	4 (2.2%)	9 (2.6%)
	C2D1		N=159	N=147	N=306
		Not At All	102 (64.2%)	83 (56.5%)	185 (60.5%)
		A Little Bit	31 (19.5%)	37 (25.2%)	68 (22.2%)
		Somewhat	11 (6.9%)	11 (7.5%)	22 (7.2%)
		Quite A Bit	11 (6.9%)	11 (7.5%)	22 (7.2%)
		Very Much	4 (2.5%)	5 (3.4%)	9 (2.9%)
	C3D1		N=130	N=103	N=233
		Not At All	85 (65.4%)	55 (53.4%)	140 (60.1%)
		A Little Bit	30 (23.1%)	30 (29.1%)	60 (25.8%)
		Somewhat	12 (9.2%)	10 (9.7%)	22 (9.4%)
		Quite A Bit	3 (2.3%)	6 (5.8%)	9 (3.9%)
		Very Much	0 (0.0%)	2 (1.9%)	2 (0.9%)
	C4D1		N=113	N=94	N=207
		Not At All	73 (64.6%)	48 (51.1%)	121 (58.5%)
		A Little Bit	25 (22.1%)	24 (25.5%)	49 (23.7%)
		Somewhat	9 (8.0%)	18 (19.1%)	27 (13.0%)
		Quite A Bit	5 (4.4%)	4 (4.3%)	9 (4.3%)
		Very Much	1 (0.9%)	0 (0.0%)	1 (0.5%)
	C5D1		N=101	N=78	N=179
		Not At All	68 (67.3%)	45 (57.7%)	113 (63.1%)
		A Little Bit	22 (21.8%)	16 (20.5%)	38 (21.2%)
		Somewhat	9 (8.9%)	14 (17.9%)	23 (12.8%)
		Quite A Bit	2 (2.0%)	2 (2.6%)	4 (2.2%)
		Very Much	0 (0.0%)	1 (1.3%)	1 (0.6%)
	C6D1		N=96	N=70	N=166
		Not At All	68 (70.8%)	38 (54.3%)	106 (63.9%)
		A Little Bit	21 (21.9%)	22 (31.4%)	43 (25.9%)
		Somewhat	5 (5.2%)	7 (10.0%)	12 (7.2%)
		Quite A Bit	2 (2.1%)	2 (2.9%)	4 (2.4%)
		Very Much	0 (0.0%)	1 (1.4%)	1 (0.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=82	N=50	N=132
		Not At All	59 (72.0%)	31 (62.0%)	90 (68.2%)
		A Little Bit	15 (18.3%)	13 (26.0%)	28 (21.2%)
		Somewhat	4 (4.9%)	5 (10.0%)	9 (6.8%)
		Quite A Bit	4 (4.9%)	1 (2.0%)	5 (3.8%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C8D1		N=78	N=46	N=124
		Not At All	55 (70.5%)	27 (58.7%)	82 (66.1%)
		A Little Bit	11 (14.1%)	12 (26.1%)	23 (18.5%)
		Somewhat	10 (12.8%)	4 (8.7%)	14 (11.3%)
		Quite A Bit	1 (1.3%)	3 (6.5%)	4 (3.2%)
		Very Much	1 (1.3%)	0 (0.0%)	1 (0.8%)
	C9D1		N=60	N=40	N=100
		Not At All	44 (73.3%)	26 (65.0%)	70 (70.0%)
		A Little Bit	11 (18.3%)	9 (22.5%)	20 (20.0%)
		Somewhat	2 (3.3%)	3 (7.5%)	5 (5.0%)
		Quite A Bit	1 (1.7%)	2 (5.0%)	3 (3.0%)
		Very Much	2 (3.3%)	0 (0.0%)	2 (2.0%)
	C10D1		N=51	N=29	N=80
		Not At All	37 (72.5%)	16 (55.2%)	53 (66.3%)
		A Little Bit	9 (17.6%)	10 (34.5%)	19 (23.8%)
		Somewhat	3 (5.9%)	2 (6.9%)	5 (6.3%)
		Quite A Bit	1 (2.0%)	1 (3.4%)	2 (2.5%)
		Very Much	1 (2.0%)	0 (0.0%)	1 (1.3%)
	C11D1		N=46	N=23	N=69
		Not At All	30 (65.2%)	13 (56.5%)	43 (62.3%)
		A Little Bit	13 (28.3%)	8 (34.8%)	21 (30.4%)
		Somewhat	2 (4.3%)	2 (8.7%)	4 (5.8%)
		Quite A Bit	1 (2.2%)	0 (0.0%)	1 (1.4%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=41	N=19	N=60
		Not At All	29 (70.7%)	11 (57.9%)	40 (66.7%)
		A Little Bit	7 (17.1%)	8 (42.1%)	15 (25.0%)
		Somewhat	4 (9.8%)	0 (0.0%)	4 (6.7%)
		Quite A Bit	1 (2.4%)	0 (0.0%)	1 (1.7%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=34	N=14	N=48
		Not At All	21 (61.8%)	5 (35.7%)	26 (54.2%)
		A Little Bit	10 (29.4%)	8 (57.1%)	18 (37.5%)
		Somewhat	1 (2.9%)	1 (7.1%)	2 (4.2%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	2 (5.9%)	0 (0.0%)	2 (4.2%)
	C14D1		N=34	N=13	N=47
		Not At All	23 (67.6%)	8 (61.5%)	31 (66.0%)
		A Little Bit	8 (23.5%)	4 (30.8%)	12 (25.5%)
		Somewhat	3 (8.8%)	1 (7.7%)	4 (8.5%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C15D1		N=29	N=13	N=42
		Not At All	18 (62.1%)	7 (53.8%)	25 (59.5%)
		A Little Bit	7 (24.1%)	3 (23.1%)	10 (23.8%)
		Somewhat	3 (10.3%)	1 (7.7%)	4 (9.5%)
		Quite A Bit	0 (0.0%)	2 (15.4%)	2 (4.8%)
		Very Much	1 (3.4%)	0 (0.0%)	1 (2.4%)
	C16D1		N=29	N=11	N=40
		Not At All	21 (72.4%)	5 (45.5%)	26 (65.0%)
		A Little Bit	7 (24.1%)	3 (27.3%)	10 (25.0%)
		Somewhat	1 (3.4%)	3 (27.3%)	4 (10.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=27	N=7	N=34
		Not At All	18 (66.7%)	4 (57.1%)	22 (64.7%)
		A Little Bit	6 (22.2%)	2 (28.6%)	8 (23.5%)
		Somewhat	3 (11.1%)	1 (14.3%)	4 (11.8%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Not At All	14 (60.9%)	5 (71.4%)	19 (63.3%)
		A Little Bit	8 (34.8%)	1 (14.3%)	9 (30.0%)
		Somewhat	1 (4.3%)	1 (14.3%)	2 (6.7%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=20	N=5	N=25
		Not At All	14 (70.0%)	1 (20.0%)	15 (60.0%)
		A Little Bit	6 (30.0%)	3 (60.0%)	9 (36.0%)
		Somewhat	0 (0.0%)	1 (20.0%)	1 (4.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=19	N=4	N=23
		Not At All	12 (63.2%)	2 (50.0%)	14 (60.9%)
		A Little Bit	7 (36.8%)	2 (50.0%)	9 (39.1%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C21D1		N=18	N=4	N=22
		Not At All	10 (55.6%)	2 (50.0%)	12 (54.5%)
		A Little Bit	7 (38.9%)	2 (50.0%)	9 (40.9%)
		Somewhat	1 (5.6%)	0 (0.0%)	1 (4.5%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C22D1		N=14	N=3	N=17
		Not At All	8 (57.1%)	1 (33.3%)	9 (52.9%)
		A Little Bit	5 (35.7%)	2 (66.7%)	7 (41.2%)
		Somewhat	1 (7.1%)	0 (0.0%)	1 (5.9%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Not At All	7 (70.0%)	1 (33.3%)	8 (61.5%)
		A Little Bit	3 (30.0%)	1 (33.3%)	4 (30.8%)
		Somewhat	0 (0.0%)	1 (33.3%)	1 (7.7%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=10	N=2	N=12
		Not At All	6 (60.0%)	1 (50.0%)	7 (58.3%)
		A Little Bit	3 (30.0%)	1 (50.0%)	4 (33.3%)
		Somewhat	1 (10.0%)	0 (0.0%)	1 (8.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=8	N=0	N=8
		Not At All	5 (62.5%)	0 (NE)	5 (62.5%)
		A Little Bit	3 (37.5%)	0 (NE)	3 (37.5%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Not At All	5 (62.5%)	1 (100.0%)	6 (66.7%)
		A Little Bit	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Somewhat	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		Not At All	6 (75.0%)	1 (100.0%)	7 (77.8%)
		A Little Bit	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Somewhat	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		Not At All	4 (57.1%)	1 (100.0%)	5 (62.5%)
		A Little Bit	2 (28.6%)	0 (0.0%)	2 (25.0%)
		Somewhat	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Not At All	3 (75.0%)	1 (100.0%)	4 (80.0%)
		A Little Bit	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Not At All	3 (75.0%)	0 (0.0%)	3 (60.0%)
		A Little Bit	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		Not At All	2 (100.0%)	0 (0.0%)	2 (66.7%)
		A Little Bit	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Not At All	2 (100.0%)	1 (100.0%)	3 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Not At All	3 (100.0%)	1 (100.0%)	4 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=126	N=127	N=253
		Not At All	71 (56.3%)	68 (53.5%)	139 (54.9%)
		A Little Bit	30 (23.8%)	35 (27.6%)	65 (25.7%)
		Somewhat	7 (5.6%)	13 (10.2%)	20 (7.9%)
		Quite A Bit	14 (11.1%)	7 (5.5%)	21 (8.3%)
		Very Much	4 (3.2%)	4 (3.1%)	8 (3.2%)
	Long Term Follow-up		N=15	N=9	N=24
		Not At All	9 (60.0%)	5 (55.6%)	14 (58.3%)
		A Little Bit	5 (33.3%)	2 (22.2%)	7 (29.2%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	1 (6.7%)	2 (22.2%)	3 (12.5%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hair Loss Amount	Baseline		N=175	N=175	N=350
		Not At All	137 (78.3%)	144 (82.3%)	281 (80.3%)
		A Little Bit	22 (12.6%)	19 (10.9%)	41 (11.7%)
		Somewhat	6 (3.4%)	6 (3.4%)	12 (3.4%)
		Quite A Bit	2 (1.1%)	3 (1.7%)	5 (1.4%)
		Very Much	8 (4.6%)	3 (1.7%)	11 (3.1%)
	C2D1		N=160	N=149	N=309
		Not At All	18 (11.3%)	71 (47.7%)	89 (28.8%)
		A Little Bit	12 (7.5%)	21 (14.1%)	33 (10.7%)
		Somewhat	10 (6.3%)	16 (10.7%)	26 (8.4%)
		Quite A Bit	28 (17.5%)	17 (11.4%)	45 (14.6%)
		Very Much	92 (57.5%)	24 (16.1%)	116 (37.5%)
	C3D1		N=120	N=104	N=224
		Not At All	54 (45.0%)	41 (39.4%)	95 (42.4%)
		A Little Bit	15 (12.5%)	24 (23.1%)	39 (17.4%)
		Somewhat	8 (6.7%)	15 (14.4%)	23 (10.3%)
		Quite A Bit	10 (8.3%)	14 (13.5%)	24 (10.7%)
		Very Much	33 (27.5%)	10 (9.6%)	43 (19.2%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=106	N=94	N=200
		Not At All	65 (61.3%)	45 (47.9%)	110 (55.0%)
		A Little Bit	12 (11.3%)	24 (25.5%)	36 (18.0%)
		Somewhat	3 (2.8%)	10 (10.6%)	13 (6.5%)
		Quite A Bit	2 (1.9%)	4 (4.3%)	6 (3.0%)
		Very Much	24 (22.6%)	11 (11.7%)	35 (17.5%)
	C5D1		N=91	N=79	N=170
		Not At All	62 (68.1%)	31 (39.2%)	93 (54.7%)
		A Little Bit	5 (5.5%)	26 (32.9%)	31 (18.2%)
		Somewhat	2 (2.2%)	15 (19.0%)	17 (10.0%)
		Quite A Bit	2 (2.2%)	3 (3.8%)	5 (2.9%)
		Very Much	20 (22.0%)	4 (5.1%)	24 (14.1%)
	C6D1		N=89	N=71	N=160
		Not At All	62 (69.7%)	37 (52.1%)	99 (61.9%)
		A Little Bit	4 (4.5%)	21 (29.6%)	25 (15.6%)
		Somewhat	4 (4.5%)	5 (7.0%)	9 (5.6%)
		Quite A Bit	1 (1.1%)	7 (9.9%)	8 (5.0%)
		Very Much	18 (20.2%)	1 (1.4%)	19 (11.9%)
	C7D1		N=74	N=56	N=130
		Not At All	55 (74.3%)	35 (62.5%)	90 (69.2%)
		A Little Bit	2 (2.7%)	14 (25.0%)	16 (12.3%)
		Somewhat	2 (2.7%)	4 (7.1%)	6 (4.6%)
		Quite A Bit	0 (0.0%)	2 (3.6%)	2 (1.5%)
		Very Much	15 (20.3%)	1 (1.8%)	16 (12.3%)
	C8D1		N=67	N=50	N=117
		Not At All	47 (70.1%)	34 (68.0%)	81 (69.2%)
		A Little Bit	2 (3.0%)	14 (28.0%)	16 (13.7%)
		Somewhat	2 (3.0%)	1 (2.0%)	3 (2.6%)
		Quite A Bit	1 (1.5%)	1 (2.0%)	2 (1.7%)
		Very Much	15 (22.4%)	0 (0.0%)	15 (12.8%)
	C9D1		N=51	N=42	N=93
		Not At All	37 (72.5%)	24 (57.1%)	61 (65.6%)
		A Little Bit	4 (7.8%)	13 (31.0%)	17 (18.3%)
		Somewhat	1 (2.0%)	3 (7.1%)	4 (4.3%)
		Quite A Bit	1 (2.0%)	2 (4.8%)	3 (3.2%)
		Very Much	8 (15.7%)	0 (0.0%)	8 (8.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=42	N=31	N=73
		Not At All	33 (78.6%)	17 (54.8%)	50 (68.5%)
		A Little Bit	0 (0.0%)	10 (32.3%)	10 (13.7%)
		Somewhat	2 (4.8%)	2 (6.5%)	4 (5.5%)
		Quite A Bit	0 (0.0%)	1 (3.2%)	1 (1.4%)
		Very Much	7 (16.7%)	1 (3.2%)	8 (11.0%)
	C11D1		N=34	N=24	N=58
		Not At All	25 (73.5%)	17 (70.8%)	42 (72.4%)
		A Little Bit	1 (2.9%)	5 (20.8%)	6 (10.3%)
		Somewhat	1 (2.9%)	0 (0.0%)	1 (1.7%)
		Quite A Bit	1 (2.9%)	2 (8.3%)	3 (5.2%)
		Very Much	6 (17.6%)	0 (0.0%)	6 (10.3%)
	C12D1		N=36	N=19	N=55
		Not At All	26 (72.2%)	11 (57.9%)	37 (67.3%)
		A Little Bit	2 (5.6%)	7 (36.8%)	9 (16.4%)
		Somewhat	1 (2.8%)	1 (5.3%)	2 (3.6%)
		Quite A Bit	1 (2.8%)	0 (0.0%)	1 (1.8%)
		Very Much	6 (16.7%)	0 (0.0%)	6 (10.9%)
	C13D1		N=29	N=14	N=43
		Not At All	21 (72.4%)	9 (64.3%)	30 (69.8%)
		A Little Bit	1 (3.4%)	4 (28.6%)	5 (11.6%)
		Somewhat	1 (3.4%)	1 (7.1%)	2 (4.7%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	6 (20.7%)	0 (0.0%)	6 (14.0%)
	C14D1		N=27	N=12	N=39
		Not At All	18 (66.7%)	9 (75.0%)	27 (69.2%)
		A Little Bit	0 (0.0%)	3 (25.0%)	3 (7.7%)
		Somewhat	2 (7.4%)	0 (0.0%)	2 (5.1%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	7 (25.9%)	0 (0.0%)	7 (17.9%)
	C15D1		N=24	N=12	N=36
		Not At All	18 (75.0%)	8 (66.7%)	26 (72.2%)
		A Little Bit	1 (4.2%)	4 (33.3%)	5 (13.9%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	5 (20.8%)	0 (0.0%)	5 (13.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=24	N=9	N=33
		Not At All	18 (75.0%)	6 (66.7%)	24 (72.7%)
		A Little Bit	1 (4.2%)	3 (33.3%)	4 (12.1%)
		Somewhat	1 (4.2%)	0 (0.0%)	1 (3.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	4 (16.7%)	0 (0.0%)	4 (12.1%)
	C17D1		N=24	N=6	N=30
		Not At All	17 (70.8%)	3 (50.0%)	20 (66.7%)
		A Little Bit	1 (4.2%)	2 (33.3%)	3 (10.0%)
		Somewhat	1 (4.2%)	0 (0.0%)	1 (3.3%)
		Quite A Bit	0 (0.0%)	1 (16.7%)	1 (3.3%)
		Very Much	5 (20.8%)	0 (0.0%)	5 (16.7%)
	C18D1		N=18	N=7	N=25
		Not At All	13 (72.2%)	5 (71.4%)	18 (72.0%)
		A Little Bit	0 (0.0%)	2 (28.6%)	2 (8.0%)
		Somewhat	1 (5.6%)	0 (0.0%)	1 (4.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	4 (22.2%)	0 (0.0%)	4 (16.0%)
	C19D1		N=17	N=6	N=23
		Not At All	11 (64.7%)	5 (83.3%)	16 (69.6%)
		A Little Bit	1 (5.9%)	1 (16.7%)	2 (8.7%)
		Somewhat	1 (5.9%)	0 (0.0%)	1 (4.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	4 (23.5%)	0 (0.0%)	4 (17.4%)
	C20D1		N=16	N=4	N=20
		Not At All	12 (75.0%)	3 (75.0%)	15 (75.0%)
		A Little Bit	1 (6.3%)	1 (25.0%)	2 (10.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	3 (18.8%)	0 (0.0%)	3 (15.0%)
	C21D1		N=15	N=4	N=19
		Not At All	11 (73.3%)	3 (75.0%)	14 (73.7%)
		A Little Bit	0 (0.0%)	1 (25.0%)	1 (5.3%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	4 (26.7%)	0 (0.0%)	4 (21.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=11	N=3	N=14
		Not At All	7 (63.6%)	3 (100.0%)	10 (71.4%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	1 (9.1%)	0 (0.0%)	1 (7.1%)
		Very Much	3 (27.3%)	0 (0.0%)	3 (21.4%)
	C23D1		N=9	N=3	N=12
		Not At All	7 (77.8%)	3 (100.0%)	10 (83.3%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	2 (22.2%)	0 (0.0%)	2 (16.7%)
	C24D1		N=9	N=2	N=11
		Not At All	8 (88.9%)	2 (100.0%)	10 (90.9%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (11.1%)	0 (0.0%)	1 (9.1%)
	C25D1		N=8	N=0	N=8
		Not At All	7 (87.5%)	0 (NE)	7 (87.5%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	1 (12.5%)	0 (NE)	1 (12.5%)
	C26D1		N=8	N=1	N=9
		Not At All	6 (75.0%)	1 (100.0%)	7 (77.8%)
		A Little Bit	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (12.5%)	0 (0.0%)	1 (11.1%)
	C27D1		N=6	N=1	N=7
		Not At All	5 (83.3%)	1 (100.0%)	6 (85.7%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (16.7%)	0 (0.0%)	1 (14.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=5	N=1	N=6
		Not At All	4 (80.0%)	1 (100.0%)	5 (83.3%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (20.0%)	0 (0.0%)	1 (16.7%)
	C29D1		N=4	N=1	N=5
		Not At All	3 (75.0%)	1 (100.0%)	4 (80.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=3	N=1	N=4
		Not At All	2 (66.7%)	1 (100.0%)	3 (75.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (33.3%)	0 (0.0%)	1 (25.0%)
	C31D1		N=2	N=1	N=3
		Not At All	2 (100.0%)	1 (100.0%)	3 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Not At All	2 (100.0%)	1 (100.0%)	3 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Not At All	3 (100.0%)	1 (100.0%)	4 (100.0%)
		A Little Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=117	N=128	N=245
		Not At All	70 (59.8%)	77 (60.2%)	147 (60.0%)
		A Little Bit	7 (6.0%)	23 (18.0%)	30 (12.2%)
		Somewhat	6 (5.1%)	16 (12.5%)	22 (9.0%)
		Quite A Bit	6 (5.1%)	2 (1.6%)	8 (3.3%)
		Very Much	28 (23.9%)	10 (7.8%)	38 (15.5%)
	Long Term		N=15	N=9	N=24
	Follow-up	Not At All	13 (86.7%)	6 (66.7%)	19 (79.2%)
		A Little Bit	0 (0.0%)	1 (11.1%)	1 (4.2%)
		Somewhat	0 (0.0%)	1 (11.1%)	1 (4.2%)
		Quite A Bit	1 (6.7%)	0 (0.0%)	1 (4.2%)
		Very Much	1 (6.7%)	1 (11.1%)	2 (8.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Fatigue Severity	Baseline		N=177	N=180	N=357
		None	39 (22.0%)	34 (18.9%)	73 (20.4%)
		Mild	67 (37.9%)	67 (37.2%)	134 (37.5%)
		Moderate	46 (26.0%)	56 (31.1%)	102 (28.6%)
		Severe	18 (10.2%)	19 (10.6%)	37 (10.4%)
		Very Severe	7 (4.0%)	4 (2.2%)	11 (3.1%)
	C2D1		N=161	N=150	N=311
		None	16 (9.9%)	13 (8.7%)	29 (9.3%)
		Mild	55 (34.2%)	54 (36.0%)	109 (35.0%)
		Moderate	51 (31.7%)	55 (36.7%)	106 (34.1%)
		Severe	32 (19.9%)	19 (12.7%)	51 (16.4%)
		Very Severe	7 (4.3%)	9 (6.0%)	16 (5.1%)
	C3D1		N=131	N=106	N=237
		None	16 (12.2%)	13 (12.3%)	29 (12.2%)
		Mild	58 (44.3%)	42 (39.6%)	100 (42.2%)
		Moderate	36 (27.5%)	35 (33.0%)	71 (30.0%)
		Severe	15 (11.5%)	14 (13.2%)	29 (12.2%)
		Very Severe	6 (4.6%)	2 (1.9%)	8 (3.4%)
	C4D1		N=118	N=97	N=215
		None	21 (17.8%)	18 (18.6%)	39 (18.1%)
		Mild	48 (40.7%)	35 (36.1%)	83 (38.6%)
		Moderate	31 (26.3%)	32 (33.0%)	63 (29.3%)
		Severe	14 (11.9%)	9 (9.3%)	23 (10.7%)
		Very Severe	4 (3.4%)	3 (3.1%)	7 (3.3%)
	C5D1		N=104	N=82	N=186
		None	24 (23.1%)	16 (19.5%)	40 (21.5%)
		Mild	36 (34.6%)	31 (37.8%)	67 (36.0%)
		Moderate	29 (27.9%)	25 (30.5%)	54 (29.0%)
		Severe	14 (13.5%)	10 (12.2%)	24 (12.9%)
		Very Severe	1 (1.0%)	0 (0.0%)	1 (0.5%)
	C6D1		N=102	N=73	N=175
		None	27 (26.5%)	17 (23.3%)	44 (25.1%)
		Mild	35 (34.3%)	25 (34.2%)	60 (34.3%)
		Moderate	31 (30.4%)	23 (31.5%)	54 (30.9%)
		Severe	6 (5.9%)	6 (8.2%)	12 (6.9%)
		Very Severe	3 (2.9%)	2 (2.7%)	5 (2.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C7D1		N=84	N=54	N=138
		None	24 (28.6%)	11 (20.4%)	35 (25.4%)
		Mild	28 (33.3%)	28 (51.9%)	56 (40.6%)
		Moderate	18 (21.4%)	13 (24.1%)	31 (22.5%)
		Severe	11 (13.1%)	2 (3.7%)	13 (9.4%)
		Very Severe	3 (3.6%)	0 (0.0%)	3 (2.2%)
	C8D1		N=80	N=51	N=131
		None	23 (28.8%)	8 (15.7%)	31 (23.7%)
		Mild	30 (37.5%)	26 (51.0%)	56 (42.7%)
		Moderate	17 (21.3%)	13 (25.5%)	30 (22.9%)
		Severe	6 (7.5%)	3 (5.9%)	9 (6.9%)
		Very Severe	4 (5.0%)	1 (2.0%)	5 (3.8%)
	C9D1		N=64	N=42	N=106
		None	19 (29.7%)	9 (21.4%)	28 (26.4%)
		Mild	23 (35.9%)	14 (33.3%)	37 (34.9%)
		Moderate	14 (21.9%)	14 (33.3%)	28 (26.4%)
		Severe	4 (6.3%)	4 (9.5%)	8 (7.5%)
		Very Severe	4 (6.3%)	1 (2.4%)	5 (4.7%)
	C10D1		N=56	N=31	N=87
		None	16 (28.6%)	2 (6.5%)	18 (20.7%)
		Mild	23 (41.1%)	13 (41.9%)	36 (41.4%)
		Moderate	10 (17.9%)	11 (35.5%)	21 (24.1%)
		Severe	6 (10.7%)	3 (9.7%)	9 (10.3%)
		Very Severe	1 (1.8%)	2 (6.5%)	3 (3.4%)
	C11D1		N=49	N=24	N=73
		None	15 (30.6%)	5 (20.8%)	20 (27.4%)
		Mild	17 (34.7%)	8 (33.3%)	25 (34.2%)
		Moderate	12 (24.5%)	9 (37.5%)	21 (28.8%)
		Severe	5 (10.2%)	2 (8.3%)	7 (9.6%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C12D1		N=43	N=20	N=63
		None	15 (34.9%)	3 (15.0%)	18 (28.6%)
		Mild	15 (34.9%)	13 (65.0%)	28 (44.4%)
		Moderate	10 (23.3%)	3 (15.0%)	13 (20.6%)
		Severe	3 (7.0%)	1 (5.0%)	4 (6.3%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C13D1		N=36	N=15	N=51
		None	9 (25.0%)	3 (20.0%)	12 (23.5%)
		Mild	16 (44.4%)	8 (53.3%)	24 (47.1%)
		Moderate	8 (22.2%)	2 (13.3%)	10 (19.6%)
		Severe	3 (8.3%)	0 (0.0%)	3 (5.9%)
		Very Severe	0 (0.0%)	2 (13.3%)	2 (3.9%)
	C14D1		N=35	N=13	N=48
		None	8 (22.9%)	2 (15.4%)	10 (20.8%)
		Mild	15 (42.9%)	5 (38.5%)	20 (41.7%)
		Moderate	9 (25.7%)	4 (30.8%)	13 (27.1%)
		Severe	3 (8.6%)	1 (7.7%)	4 (8.3%)
		Very Severe	0 (0.0%)	1 (7.7%)	1 (2.1%)
	C15D1		N=30	N=14	N=44
		None	7 (23.3%)	0 (0.0%)	7 (15.9%)
		Mild	11 (36.7%)	7 (50.0%)	18 (40.9%)
		Moderate	9 (30.0%)	5 (35.7%)	14 (31.8%)
		Severe	2 (6.7%)	1 (7.1%)	3 (6.8%)
		Very Severe	1 (3.3%)	1 (7.1%)	2 (4.5%)
	C16D1		N=30	N=11	N=41
		None	11 (36.7%)	1 (9.1%)	12 (29.3%)
		Mild	9 (30.0%)	6 (54.5%)	15 (36.6%)
		Moderate	6 (20.0%)	3 (27.3%)	9 (22.0%)
		Severe	3 (10.0%)	0 (0.0%)	3 (7.3%)
		Very Severe	1 (3.3%)	1 (9.1%)	2 (4.9%)
	C17D1		N=28	N=7	N=35
		None	8 (28.6%)	0 (0.0%)	8 (22.9%)
		Mild	12 (42.9%)	3 (42.9%)	15 (42.9%)
		Moderate	6 (21.4%)	2 (28.6%)	8 (22.9%)
		Severe	2 (7.1%)	1 (14.3%)	3 (8.6%)
		Very Severe	0 (0.0%)	1 (14.3%)	1 (2.9%)
	C18D1		N=23	N=7	N=30
		None	7 (30.4%)	1 (14.3%)	8 (26.7%)
		Mild	10 (43.5%)	3 (42.9%)	13 (43.3%)
		Moderate	5 (21.7%)	2 (28.6%)	7 (23.3%)
		Severe	1 (4.3%)	0 (0.0%)	1 (3.3%)
		Very Severe	0 (0.0%)	1 (14.3%)	1 (3.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C19D1		N=21	N=6	N=27
		None	5 (23.8%)	0 (0.0%)	5 (18.5%)
		Mild	10 (47.6%)	3 (50.0%)	13 (48.1%)
		Moderate	4 (19.0%)	2 (33.3%)	6 (22.2%)
		Severe	2 (9.5%)	1 (16.7%)	3 (11.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=20	N=4	N=24
		None	5 (25.0%)	0 (0.0%)	5 (20.8%)
		Mild	11 (55.0%)	2 (50.0%)	13 (54.2%)
		Moderate	3 (15.0%)	2 (50.0%)	5 (20.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (5.0%)	0 (0.0%)	1 (4.2%)
	C21D1		N=18	N=4	N=22
		None	6 (33.3%)	0 (0.0%)	6 (27.3%)
		Mild	7 (38.9%)	1 (25.0%)	8 (36.4%)
		Moderate	4 (22.2%)	3 (75.0%)	7 (31.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (5.6%)	0 (0.0%)	1 (4.5%)
	C22D1		N=15	N=3	N=18
		None	4 (26.7%)	0 (0.0%)	4 (22.2%)
		Mild	8 (53.3%)	1 (33.3%)	9 (50.0%)
		Moderate	3 (20.0%)	2 (66.7%)	5 (27.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		None	2 (20.0%)	0 (0.0%)	2 (15.4%)
		Mild	4 (40.0%)	2 (66.7%)	6 (46.2%)
		Moderate	3 (30.0%)	1 (33.3%)	4 (30.8%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (10.0%)	0 (0.0%)	1 (7.7%)
	C24D1		N=10	N=2	N=12
		None	2 (20.0%)	1 (50.0%)	3 (25.0%)
		Mild	5 (50.0%)	0 (0.0%)	5 (41.7%)
		Moderate	2 (20.0%)	1 (50.0%)	3 (25.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	1 (10.0%)	0 (0.0%)	1 (8.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C25D1		N=9	N=0	N=9
		None	3 (33.3%)	0 (NE)	3 (33.3%)
		Mild	4 (44.4%)	0 (NE)	4 (44.4%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	2 (22.2%)	0 (NE)	2 (22.2%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		None	2 (25.0%)	1 (100.0%)	3 (33.3%)
		Mild	4 (50.0%)	0 (0.0%)	4 (44.4%)
		Moderate	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Severe	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		None	2 (25.0%)	1 (100.0%)	3 (33.3%)
		Mild	4 (50.0%)	0 (0.0%)	4 (44.4%)
		Moderate	2 (25.0%)	0 (0.0%)	2 (22.2%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=7	N=1	N=8
		None	2 (28.6%)	1 (100.0%)	3 (37.5%)
		Mild	3 (42.9%)	0 (0.0%)	3 (37.5%)
		Moderate	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Severe	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		None	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Mild	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		None	2 (50.0%)	0 (0.0%)	2 (40.0%)
		Mild	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C31D1		N=2	N=1	N=3
		None	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Mild	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		None	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Mild	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Moderate	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		None	2 (66.7%)	0 (0.0%)	2 (50.0%)
		Mild	1 (33.3%)	1 (100.0%)	2 (50.0%)
		Moderate	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		None	1 (50.0%)	0 (NE)	1 (50.0%)
		Mild	1 (50.0%)	0 (NE)	1 (50.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C37D1		N=3	N=0	N=3
		None	2 (66.7%)	0 (NE)	2 (66.7%)
		Mild	1 (33.3%)	0 (NE)	1 (33.3%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		None	2 (100.0%)	0 (NE)	2 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		None	0 (0.0%)	0 (NE)	0 (0.0%)
		Mild	1 (50.0%)	0 (NE)	1 (50.0%)
		Moderate	1 (50.0%)	0 (NE)	1 (50.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C43D1		N=1	N=0	N=1
		None	1 (100.0%)	0 (NE)	1 (100.0%)
		Mild	0 (0.0%)	0 (NE)	0 (0.0%)
		Moderate	0 (0.0%)	0 (NE)	0 (0.0%)
		Severe	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Severe	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=135	N=132	N=267
		None	23 (17.0%)	22 (16.7%)	45 (16.9%)
		Mild	38 (28.1%)	37 (28.0%)	75 (28.1%)
		Moderate	41 (30.4%)	45 (34.1%)	86 (32.2%)
		Severe	19 (14.1%)	20 (15.2%)	39 (14.6%)
		Very Severe	14 (10.4%)	8 (6.1%)	22 (8.2%)
	Long Term		N=15	N=9	N=24
	Follow-up	None	2 (13.3%)	0 (0.0%)	2 (8.3%)
		Mild	6 (40.0%)	4 (44.4%)	10 (41.7%)
		Moderate	5 (33.3%)	3 (33.3%)	8 (33.3%)
		Severe	2 (13.3%)	0 (0.0%)	2 (8.3%)
		Very Severe	0 (0.0%)	2 (22.2%)	2 (8.3%)
Fatigue Interference	Baseline		N=176	N=179	N=355
		Not At All	52 (29.5%)	53 (29.6%)	105 (29.6%)
		A Little Bit	65 (36.9%)	61 (34.1%)	126 (35.5%)
		Somewhat	34 (19.3%)	40 (22.3%)	74 (20.8%)
		Quite A Bit	19 (10.8%)	21 (11.7%)	40 (11.3%)
		Very Much	6 (3.4%)	4 (2.2%)	10 (2.8%)
	C2D1		N=159	N=147	N=306
		Not At All	31 (19.5%)	34 (23.1%)	65 (21.2%)
		A Little Bit	63 (39.6%)	48 (32.7%)	111 (36.3%)
		Somewhat	24 (15.1%)	39 (26.5%)	63 (20.6%)
		Quite A Bit	32 (20.1%)	15 (10.2%)	47 (15.4%)
		Very Much	9 (5.7%)	11 (7.5%)	20 (6.5%)
	C3D1		N=132	N=106	N=238
		Not At All	38 (28.8%)	30 (28.3%)	68 (28.6%)
		A Little Bit	49 (37.1%)	40 (37.7%)	89 (37.4%)
		Somewhat	23 (17.4%)	22 (20.8%)	45 (18.9%)
		Quite A Bit	16 (12.1%)	12 (11.3%)	28 (11.8%)
		Very Much	6 (4.5%)	2 (1.9%)	8 (3.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=117	N=96	N=213
		Not At All	38 (32.5%)	31 (32.3%)	69 (32.4%)
		A Little Bit	39 (33.3%)	34 (35.4%)	73 (34.3%)
		Somewhat	22 (18.8%)	18 (18.8%)	40 (18.8%)
		Quite A Bit	13 (11.1%)	10 (10.4%)	23 (10.8%)
		Very Much	5 (4.3%)	3 (3.1%)	8 (3.8%)
	C5D1		N=99	N=80	N=179
		Not At All	31 (31.3%)	25 (31.3%)	56 (31.3%)
		A Little Bit	35 (35.4%)	29 (36.3%)	64 (35.8%)
		Somewhat	17 (17.2%)	18 (22.5%)	35 (19.6%)
		Quite A Bit	12 (12.1%)	8 (10.0%)	20 (11.2%)
		Very Much	4 (4.0%)	0 (0.0%)	4 (2.2%)
	C6D1		N=97	N=73	N=170
		Not At All	35 (36.1%)	24 (32.9%)	59 (34.7%)
		A Little Bit	31 (32.0%)	24 (32.9%)	55 (32.4%)
		Somewhat	18 (18.6%)	12 (16.4%)	30 (17.6%)
		Quite A Bit	9 (9.3%)	12 (16.4%)	21 (12.4%)
		Very Much	4 (4.1%)	1 (1.4%)	5 (2.9%)
	C7D1		N=83	N=51	N=134
		Not At All	34 (41.0%)	19 (37.3%)	53 (39.6%)
		A Little Bit	23 (27.7%)	23 (45.1%)	46 (34.3%)
		Somewhat	15 (18.1%)	6 (11.8%)	21 (15.7%)
		Quite A Bit	9 (10.8%)	2 (3.9%)	11 (8.2%)
		Very Much	2 (2.4%)	1 (2.0%)	3 (2.2%)
	C8D1		N=79	N=50	N=129
		Not At All	31 (39.2%)	17 (34.0%)	48 (37.2%)
		A Little Bit	24 (30.4%)	21 (42.0%)	45 (34.9%)
		Somewhat	16 (20.3%)	5 (10.0%)	21 (16.3%)
		Quite A Bit	4 (5.1%)	6 (12.0%)	10 (7.8%)
		Very Much	4 (5.1%)	1 (2.0%)	5 (3.9%)
	C9D1		N=62	N=41	N=103
		Not At All	23 (37.1%)	13 (31.7%)	36 (35.0%)
		A Little Bit	20 (32.3%)	14 (34.1%)	34 (33.0%)
		Somewhat	12 (19.4%)	8 (19.5%)	20 (19.4%)
		Quite A Bit	3 (4.8%)	5 (12.2%)	8 (7.8%)
		Very Much	4 (6.5%)	1 (2.4%)	5 (4.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=54	N=29	N=83
		Not At All	24 (44.4%)	6 (20.7%)	30 (36.1%)
		A Little Bit	16 (29.6%)	15 (51.7%)	31 (37.3%)
		Somewhat	9 (16.7%)	2 (6.9%)	11 (13.3%)
		Quite A Bit	4 (7.4%)	5 (17.2%)	9 (10.8%)
		Very Much	1 (1.9%)	1 (3.4%)	2 (2.4%)
	C11D1		N=46	N=24	N=70
		Not At All	20 (43.5%)	7 (29.2%)	27 (38.6%)
		A Little Bit	14 (30.4%)	13 (54.2%)	27 (38.6%)
		Somewhat	6 (13.0%)	3 (12.5%)	9 (12.9%)
		Quite A Bit	5 (10.9%)	1 (4.2%)	6 (8.6%)
		Very Much	1 (2.2%)	0 (0.0%)	1 (1.4%)
	C12D1		N=39	N=20	N=59
		Not At All	16 (41.0%)	6 (30.0%)	22 (37.3%)
		A Little Bit	16 (41.0%)	11 (55.0%)	27 (45.8%)
		Somewhat	4 (10.3%)	2 (10.0%)	6 (10.2%)
		Quite A Bit	3 (7.7%)	1 (5.0%)	4 (6.8%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C13D1		N=35	N=15	N=50
		Not At All	11 (31.4%)	4 (26.7%)	15 (30.0%)
		A Little Bit	15 (42.9%)	8 (53.3%)	23 (46.0%)
		Somewhat	6 (17.1%)	1 (6.7%)	7 (14.0%)
		Quite A Bit	2 (5.7%)	0 (0.0%)	2 (4.0%)
		Very Much	1 (2.9%)	2 (13.3%)	3 (6.0%)
	C14D1		N=33	N=13	N=46
		Not At All	14 (42.4%)	2 (15.4%)	16 (34.8%)
		A Little Bit	11 (33.3%)	8 (61.5%)	19 (41.3%)
		Somewhat	6 (18.2%)	2 (15.4%)	8 (17.4%)
		Quite A Bit	2 (6.1%)	0 (0.0%)	2 (4.3%)
		Very Much	0 (0.0%)	1 (7.7%)	1 (2.2%)
	C15D1		N=29	N=14	N=43
		Not At All	7 (24.1%)	4 (28.6%)	11 (25.6%)
		A Little Bit	13 (44.8%)	5 (35.7%)	18 (41.9%)
		Somewhat	5 (17.2%)	3 (21.4%)	8 (18.6%)
		Quite A Bit	3 (10.3%)	1 (7.1%)	4 (9.3%)
		Very Much	1 (3.4%)	1 (7.1%)	2 (4.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=29	N=11	N=40
		Not At All	14 (48.3%)	2 (18.2%)	16 (40.0%)
		A Little Bit	6 (20.7%)	5 (45.5%)	11 (27.5%)
		Somewhat	7 (24.1%)	3 (27.3%)	10 (25.0%)
		Quite A Bit	1 (3.4%)	0 (0.0%)	1 (2.5%)
		Very Much	1 (3.4%)	1 (9.1%)	2 (5.0%)
	C17D1		N=26	N=7	N=33
		Not At All	7 (26.9%)	2 (28.6%)	9 (27.3%)
		A Little Bit	12 (46.2%)	2 (28.6%)	14 (42.4%)
		Somewhat	6 (23.1%)	2 (28.6%)	8 (24.2%)
		Quite A Bit	1 (3.8%)	1 (14.3%)	2 (6.1%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C18D1		N=23	N=7	N=30
		Not At All	8 (34.8%)	3 (42.9%)	11 (36.7%)
		A Little Bit	9 (39.1%)	2 (28.6%)	11 (36.7%)
		Somewhat	6 (26.1%)	1 (14.3%)	7 (23.3%)
		Quite A Bit	0 (0.0%)	1 (14.3%)	1 (3.3%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C19D1		N=21	N=5	N=26
		Not At All	7 (33.3%)	1 (20.0%)	8 (30.8%)
		A Little Bit	8 (38.1%)	2 (40.0%)	10 (38.5%)
		Somewhat	4 (19.0%)	2 (40.0%)	6 (23.1%)
		Quite A Bit	2 (9.5%)	0 (0.0%)	2 (7.7%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C20D1		N=18	N=4	N=22
		Not At All	6 (33.3%)	1 (25.0%)	7 (31.8%)
		A Little Bit	9 (50.0%)	1 (25.0%)	10 (45.5%)
		Somewhat	2 (11.1%)	2 (50.0%)	4 (18.2%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (5.6%)	0 (0.0%)	1 (4.5%)
	C21D1		N=18	N=4	N=22
		Not At All	8 (44.4%)	0 (0.0%)	8 (36.4%)
		A Little Bit	4 (22.2%)	3 (75.0%)	7 (31.8%)
		Somewhat	5 (27.8%)	1 (25.0%)	6 (27.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (5.6%)	0 (0.0%)	1 (4.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=15	N=3	N=18
		Not At All	7 (46.7%)	0 (0.0%)	7 (38.9%)
		A Little Bit	5 (33.3%)	3 (100.0%)	8 (44.4%)
		Somewhat	3 (20.0%)	0 (0.0%)	3 (16.7%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=10	N=3	N=13
		Not At All	5 (50.0%)	0 (0.0%)	5 (38.5%)
		A Little Bit	3 (30.0%)	3 (100.0%)	6 (46.2%)
		Somewhat	1 (10.0%)	0 (0.0%)	1 (7.7%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (10.0%)	0 (0.0%)	1 (7.7%)
	C24D1		N=10	N=2	N=12
		Not At All	3 (30.0%)	1 (50.0%)	4 (33.3%)
		A Little Bit	4 (40.0%)	0 (0.0%)	4 (33.3%)
		Somewhat	2 (20.0%)	1 (50.0%)	3 (25.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	1 (10.0%)	0 (0.0%)	1 (8.3%)
	C25D1		N=8	N=0	N=8
		Not At All	4 (50.0%)	0 (NE)	4 (50.0%)
		A Little Bit	2 (25.0%)	0 (NE)	2 (25.0%)
		Somewhat	1 (12.5%)	0 (NE)	1 (12.5%)
		Quite A Bit	1 (12.5%)	0 (NE)	1 (12.5%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=8	N=1	N=9
		Not At All	3 (37.5%)	1 (100.0%)	4 (44.4%)
		A Little Bit	3 (37.5%)	0 (0.0%)	3 (33.3%)
		Somewhat	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Quite A Bit	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=8	N=1	N=9
		Not At All	3 (37.5%)	1 (100.0%)	4 (44.4%)
		A Little Bit	4 (50.0%)	0 (0.0%)	4 (44.4%)
		Somewhat	1 (12.5%)	0 (0.0%)	1 (11.1%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=7	N=1	N=8
		Not At All	2 (28.6%)	1 (100.0%)	3 (37.5%)
		A Little Bit	4 (57.1%)	0 (0.0%)	4 (50.0%)
		Somewhat	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Not At All	1 (25.0%)	0 (0.0%)	1 (20.0%)
		A Little Bit	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Somewhat	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Quite A Bit	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Not At All	2 (50.0%)	0 (0.0%)	2 (40.0%)
		A Little Bit	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Not At All	1 (50.0%)	0 (0.0%)	1 (33.3%)
		A Little Bit	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Not At All	0 (0.0%)	0 (0.0%)	0 (0.0%)
		A Little Bit	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Somewhat	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Not At All	2 (66.7%)	0 (0.0%)	2 (50.0%)
		A Little Bit	1 (33.3%)	1 (100.0%)	2 (50.0%)
		Somewhat	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Very Much	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=1	N=0	N=1
		Not At All	0 (0.0%)	0 (NE)	0 (0.0%)
		A Little Bit	1 (100.0%)	0 (NE)	1 (100.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	1 (50.0%)	0 (NE)	1 (50.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	1 (50.0%)	0 (NE)	1 (50.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.4
Distribution of Responses to PRO-CTCAE Items by Visit
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		Not At All	2 (100.0%)	0 (NE)	2 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Not At All	1 (50.0%)	0 (NE)	1 (50.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	1 (50.0%)	0 (NE)	1 (50.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Not At All	1 (100.0%)	0 (NE)	1 (100.0%)
		A Little Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Somewhat	0 (0.0%)	0 (NE)	0 (0.0%)
		Quite A Bit	0 (0.0%)	0 (NE)	0 (0.0%)
		Very Much	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=127	N=130	N=257
		Not At All	28 (22.0%)	33 (25.4%)	61 (23.7%)
		A Little Bit	34 (26.8%)	38 (29.2%)	72 (28.0%)
		Somewhat	35 (27.6%)	38 (29.2%)	73 (28.4%)
		Quite A Bit	13 (10.2%)	11 (8.5%)	24 (9.3%)
		Very Much	17 (13.4%)	10 (7.7%)	27 (10.5%)
	Long Term Follow-up		N=14	N=9	N=23
		Not At All	6 (42.9%)	1 (11.1%)	7 (30.4%)
		A Little Bit	4 (28.6%)	4 (44.4%)	8 (34.8%)
		Somewhat	2 (14.3%)	2 (22.2%)	4 (17.4%)
		Quite A Bit	2 (14.3%)	0 (0.0%)	2 (8.7%)
		Very Much	0 (0.0%)	2 (22.2%)	2 (8.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given scheduled visit. PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Decreased Appetite Severity	C2D1		N=150	N=142	N=292
		Worsened by ≥3 Categories	4 (2.7%)	2 (1.4%)	6 (2.1%)
		Worsened by 2 Categories	14 (9.3%)	15 (10.6%)	29 (9.9%)
		Worsened by 1 Category	24 (16.0%)	32 (22.5%)	56 (19.2%)
		No Change	83 (55.3%)	71 (50.0%)	154 (52.7%)
		Improved by ≥1 Categories	25 (16.7%)	22 (15.5%)	47 (16.1%)
	C3D1		N=116	N=101	N=217
		Worsened by ≥3 Categories	3 (2.6%)	2 (2.0%)	5 (2.3%)
		Worsened by 2 Categories	9 (7.8%)	7 (6.9%)	16 (7.4%)
		Worsened by 1 Category	13 (11.2%)	17 (16.8%)	30 (13.8%)
		No Change	62 (53.4%)	48 (47.5%)	110 (50.7%)
		Improved by ≥1 Categories	29 (25.0%)	27 (26.7%)	56 (25.8%)
	C4D1		N=106	N=92	N=198
		Worsened by ≥3 Categories	1 (0.9%)	1 (1.1%)	2 (1.0%)
		Worsened by 2 Categories	5 (4.7%)	6 (6.5%)	11 (5.6%)
		Worsened by 1 Category	23 (21.7%)	18 (19.6%)	41 (20.7%)
		No Change	50 (47.2%)	39 (42.4%)	89 (44.9%)
		Improved by ≥1 Categories	27 (25.5%)	28 (30.4%)	55 (27.8%)
	C5D1		N=93	N=79	N=172
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (3.2%)	7 (8.9%)	10 (5.8%)
		Worsened by 1 Category	18 (19.4%)	11 (13.9%)	29 (16.9%)
		No Change	46 (49.5%)	36 (45.6%)	82 (47.7%)
		Improved by ≥1 Categories	26 (28.0%)	25 (31.6%)	51 (29.7%)
	C6D1		N=90	N=70	N=160
		Worsened by ≥3 Categories	1 (1.1%)	1 (1.4%)	2 (1.3%)
		Worsened by 2 Categories	6 (6.7%)	4 (5.7%)	10 (6.3%)
		Worsened by 1 Category	13 (14.4%)	14 (20.0%)	27 (16.9%)
		No Change	46 (51.1%)	31 (44.3%)	77 (48.1%)
		Improved by ≥1 Categories	24 (26.7%)	20 (28.6%)	44 (27.5%)
	C7D1		N=75	N=53	N=128
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (2.7%)	0 (0.0%)	2 (1.6%)
		Worsened by 1 Category	8 (10.7%)	10 (18.9%)	18 (14.1%)
		No Change	41 (54.7%)	20 (37.7%)	61 (47.7%)
		Improved by ≥1 Categories	24 (32.0%)	23 (43.4%)	47 (36.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C8D1		N=70	N=48	N=118
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (2.9%)	0 (0.0%)	2 (1.7%)
		Worsened by 1 Category	7 (10.0%)	8 (16.7%)	15 (12.7%)
		No Change	41 (58.6%)	20 (41.7%)	61 (51.7%)
		Improved by ≥1 Categories	20 (28.6%)	20 (41.7%)	40 (33.9%)
	C9D1		N=57	N=40	N=97
		Worsened by ≥3 Categories	2 (3.5%)	0 (0.0%)	2 (2.1%)
		Worsened by 2 Categories	3 (5.3%)	2 (5.0%)	5 (5.2%)
		Worsened by 1 Category	6 (10.5%)	5 (12.5%)	11 (11.3%)
		No Change	30 (52.6%)	17 (42.5%)	47 (48.5%)
		Improved by ≥1 Categories	16 (28.1%)	16 (40.0%)	32 (33.0%)
	C10D1		N=50	N=29	N=79
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.0%)	2 (6.9%)	3 (3.8%)
		Worsened by 1 Category	4 (8.0%)	4 (13.8%)	8 (10.1%)
		No Change	30 (60.0%)	10 (34.5%)	40 (50.6%)
		Improved by ≥1 Categories	15 (30.0%)	13 (44.8%)	28 (35.4%)
	C11D1		N=43	N=23	N=66
		Worsened by ≥3 Categories	1 (2.3%)	0 (0.0%)	1 (1.5%)
		Worsened by 2 Categories	0 (0.0%)	1 (4.3%)	1 (1.5%)
		Worsened by 1 Category	6 (14.0%)	2 (8.7%)	8 (12.1%)
		No Change	21 (48.8%)	8 (34.8%)	29 (43.9%)
		Improved by ≥1 Categories	15 (34.9%)	12 (52.2%)	27 (40.9%)
	C12D1		N=39	N=19	N=58
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.6%)	0 (0.0%)	1 (1.7%)
		Worsened by 1 Category	4 (10.3%)	1 (5.3%)	5 (8.6%)
		No Change	22 (56.4%)	10 (52.6%)	32 (55.2%)
		Improved by ≥1 Categories	12 (30.8%)	8 (42.1%)	20 (34.5%)
	C13D1		N=31	N=14	N=45
		Worsened by ≥3 Categories	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Worsened by 2 Categories	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Worsened by 1 Category	4 (12.9%)	1 (7.1%)	5 (11.1%)
		No Change	16 (51.6%)	8 (57.1%)	24 (53.3%)
		Improved by ≥1 Categories	9 (29.0%)	5 (35.7%)	14 (31.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (3.2%)	0 (0.0%)	1 (2.3%)
		Worsened by 1 Category	4 (12.9%)	0 (0.0%)	4 (9.3%)
		No Change	18 (58.1%)	8 (66.7%)	26 (60.5%)
		Improved by ≥1 Categories	8 (25.8%)	4 (33.3%)	12 (27.9%)
	C15D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (7.7%)	0 (0.0%)	2 (5.1%)
		Worsened by 1 Category	3 (11.5%)	1 (7.7%)	4 (10.3%)
		No Change	14 (53.8%)	7 (53.8%)	21 (53.8%)
		Improved by ≥1 Categories	7 (26.9%)	5 (38.5%)	12 (30.8%)
	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	1 (3.8%)	0 (0.0%)	1 (2.8%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (11.5%)	1 (10.0%)	4 (11.1%)
		No Change	15 (57.7%)	5 (50.0%)	20 (55.6%)
		Improved by ≥1 Categories	7 (26.9%)	4 (40.0%)	11 (30.6%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.2%)	0 (0.0%)	1 (3.2%)
		Worsened by 1 Category	1 (4.2%)	0 (0.0%)	1 (3.2%)
		No Change	15 (62.5%)	3 (42.9%)	18 (58.1%)
		Improved by ≥1 Categories	7 (29.2%)	4 (57.1%)	11 (35.5%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (10.0%)	0 (0.0%)	2 (7.4%)
		Worsened by 1 Category	1 (5.0%)	0 (0.0%)	1 (3.7%)
		No Change	11 (55.0%)	5 (71.4%)	16 (59.3%)
		Improved by ≥1 Categories	6 (30.0%)	2 (28.6%)	8 (29.6%)
	C19D1		N=19	N=6	N=25
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (10.5%)	1 (16.7%)	3 (12.0%)
		No Change	11 (57.9%)	3 (50.0%)	14 (56.0%)
		Improved by ≥1 Categories	6 (31.6%)	2 (33.3%)	8 (32.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (10.5%)	0 (0.0%)	2 (8.7%)
		No Change	11 (57.9%)	1 (25.0%)	12 (52.2%)
		Improved by ≥1 Categories	6 (31.6%)	3 (75.0%)	9 (39.1%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	11 (64.7%)	2 (50.0%)	13 (61.9%)
		Improved by ≥1 Categories	6 (35.3%)	2 (50.0%)	8 (38.1%)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (6.7%)	0 (0.0%)	1 (5.6%)
		No Change	11 (73.3%)	1 (33.3%)	12 (66.7%)
		Improved by ≥1 Categories	3 (20.0%)	2 (66.7%)	5 (27.8%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (8.3%)
		No Change	6 (66.7%)	1 (33.3%)	7 (58.3%)
		Improved by ≥1 Categories	2 (22.2%)	2 (66.7%)	4 (33.3%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (9.1%)
		No Change	7 (77.8%)	1 (50.0%)	8 (72.7%)
		Improved by ≥1 Categories	1 (11.1%)	1 (50.0%)	2 (18.2%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (12.5%)	0 (NE)	1 (12.5%)
		No Change	5 (62.5%)	0 (NE)	5 (62.5%)
		Improved by ≥1 Categories	2 (25.0%)	0 (NE)	2 (25.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (83.3%)	1 (100.0%)	6 (85.7%)
		Improved by ≥1 Categories	1 (16.7%)	0 (0.0%)	1 (14.3%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Improved by ≥1 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (33.3%)
		No Change	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	1 (100.0%)	2 (66.7%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (25.0%)
		No Change	3 (100.0%)	0 (0.0%)	3 (75.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (NE)	1 (33.3%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	EOT		N=124	N=123	N=247
		Worsened by ≥3 Categories	5 (4.0%)	5 (4.1%)	10 (4.0%)
		Worsened by 2 Categories	9 (7.3%)	17 (13.8%)	26 (10.5%)
		Worsened by 1 Category	23 (18.5%)	17 (13.8%)	40 (16.2%)
		No Change	65 (52.4%)	58 (47.2%)	123 (49.8%)
		Improved by ≥1 Categories	22 (17.7%)	26 (21.1%)	48 (19.4%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	1 (7.1%)	2 (22.2%)	3 (13.0%)
		Worsened by 2 Categories	1 (7.1%)	1 (11.1%)	2 (8.7%)
		Worsened by 1 Category	1 (7.1%)	0 (0.0%)	1 (4.3%)
		No Change	9 (64.3%)	6 (66.7%)	15 (65.2%)
		Improved by ≥1 Categories	2 (14.3%)	0 (0.0%)	2 (8.7%)
Decreased Appetite Interference	C2D1		N=147	N=136	N=283
		Worsened by ≥3 Categories	2 (1.4%)	2 (1.5%)	4 (1.4%)
		Worsened by 2 Categories	7 (4.8%)	5 (3.7%)	12 (4.2%)
		Worsened by 1 Category	25 (17.0%)	24 (17.6%)	49 (17.3%)
		No Change	98 (66.7%)	88 (64.7%)	186 (65.7%)
		Improved by ≥1 Categories	15 (10.2%)	17 (12.5%)	32 (11.3%)
	C3D1		N=112	N=98	N=210
		Worsened by ≥3 Categories	1 (0.9%)	1 (1.0%)	2 (1.0%)
		Worsened by 2 Categories	5 (4.5%)	5 (5.1%)	10 (4.8%)
		Worsened by 1 Category	9 (8.0%)	11 (11.2%)	20 (9.5%)
		No Change	81 (72.3%)	63 (64.3%)	144 (68.6%)
		Improved by ≥1 Categories	16 (14.3%)	18 (18.4%)	34 (16.2%)
	C4D1		N=103	N=88	N=191
		Worsened by ≥3 Categories	2 (1.9%)	1 (1.1%)	3 (1.6%)
		Worsened by 2 Categories	1 (1.0%)	4 (4.5%)	5 (2.6%)
		Worsened by 1 Category	13 (12.6%)	14 (15.9%)	27 (14.1%)
		No Change	73 (70.9%)	53 (60.2%)	126 (66.0%)
		Improved by ≥1 Categories	14 (13.6%)	16 (18.2%)	30 (15.7%)
	C5D1		N=90	N=73	N=163
		Worsened by ≥3 Categories	1 (1.1%)	0 (0.0%)	1 (0.6%)
		Worsened by 2 Categories	3 (3.3%)	4 (5.5%)	7 (4.3%)
		Worsened by 1 Category	11 (12.2%)	8 (11.0%)	19 (11.7%)
		No Change	58 (64.4%)	45 (61.6%)	103 (63.2%)
		Improved by ≥1 Categories	17 (18.9%)	16 (21.9%)	33 (20.2%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C6D1		N=84	N=64	N=148
		Worsened by ≥3 Categories	1 (1.2%)	2 (3.1%)	3 (2.0%)
		Worsened by 2 Categories	1 (1.2%)	4 (6.3%)	5 (3.4%)
		Worsened by 1 Category	14 (16.7%)	8 (12.5%)	22 (14.9%)
		No Change	55 (65.5%)	39 (60.9%)	94 (63.5%)
		Improved by ≥1 Categories	13 (15.5%)	11 (17.2%)	24 (16.2%)
	C7D1		N=74	N=49	N=123
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (1.4%)	1 (2.0%)	2 (1.6%)
		Worsened by 1 Category	4 (5.4%)	5 (10.2%)	9 (7.3%)
		No Change	55 (74.3%)	34 (69.4%)	89 (72.4%)
		Improved by ≥1 Categories	14 (18.9%)	9 (18.4%)	23 (18.7%)
	C8D1		N=67	N=43	N=110
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (1.5%)	0 (0.0%)	1 (0.9%)
		Worsened by 1 Category	4 (6.0%)	5 (11.6%)	9 (8.2%)
		No Change	51 (76.1%)	27 (62.8%)	78 (70.9%)
		Improved by ≥1 Categories	11 (16.4%)	11 (25.6%)	22 (20.0%)
	C9D1		N=53	N=39	N=92
		Worsened by ≥3 Categories	1 (1.9%)	0 (0.0%)	1 (1.1%)
		Worsened by 2 Categories	1 (1.9%)	1 (2.6%)	2 (2.2%)
		Worsened by 1 Category	6 (11.3%)	5 (12.8%)	11 (12.0%)
		No Change	34 (64.2%)	24 (61.5%)	58 (63.0%)
		Improved by ≥1 Categories	11 (20.8%)	9 (23.1%)	20 (21.7%)
	C10D1		N=47	N=28	N=75
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	3 (10.7%)	3 (4.0%)
		Worsened by 1 Category	5 (10.6%)	1 (3.6%)	6 (8.0%)
		No Change	33 (70.2%)	18 (64.3%)	51 (68.0%)
		Improved by ≥1 Categories	9 (19.1%)	6 (21.4%)	15 (20.0%)
	C11D1		N=41	N=22	N=63
		Worsened by ≥3 Categories	1 (2.4%)	1 (4.5%)	2 (3.2%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	4 (9.8%)	1 (4.5%)	5 (7.9%)
		No Change	27 (65.9%)	16 (72.7%)	43 (68.3%)
		Improved by ≥1 Categories	9 (22.0%)	4 (18.2%)	13 (20.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C12D1		N=37	N=18	N=55
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.7%)	0 (0.0%)	1 (1.8%)
		Worsened by 1 Category	3 (8.1%)	1 (5.6%)	4 (7.3%)
		No Change	27 (73.0%)	13 (72.2%)	40 (72.7%)
		Improved by ≥1 Categories	6 (16.2%)	4 (22.2%)	10 (18.2%)
	C13D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	1 (3.8%)	0 (0.0%)	1 (2.6%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (11.5%)	0 (0.0%)	3 (7.7%)
		No Change	18 (69.2%)	10 (76.9%)	28 (71.8%)
		Improved by ≥1 Categories	4 (15.4%)	3 (23.1%)	7 (17.9%)
	C14D1		N=30	N=11	N=41
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	5 (16.7%)	1 (9.1%)	6 (14.6%)
		No Change	20 (66.7%)	7 (63.6%)	27 (65.9%)
		Improved by ≥1 Categories	5 (16.7%)	3 (27.3%)	8 (19.5%)
	C15D1		N=25	N=11	N=36
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.0%)	0 (0.0%)	1 (2.8%)
		Worsened by 1 Category	2 (8.0%)	1 (9.1%)	3 (8.3%)
		No Change	18 (72.0%)	7 (63.6%)	25 (69.4%)
		Improved by ≥1 Categories	4 (16.0%)	3 (27.3%)	7 (19.4%)
	C16D1		N=24	N=10	N=34
		Worsened by ≥3 Categories	1 (4.2%)	0 (0.0%)	1 (2.9%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (8.3%)	2 (20.0%)	4 (11.8%)
		No Change	16 (66.7%)	7 (70.0%)	23 (67.6%)
		Improved by ≥1 Categories	5 (20.8%)	1 (10.0%)	6 (17.6%)
	C17D1		N=23	N=7	N=30
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.3%)	0 (0.0%)	1 (3.3%)
		Worsened by 1 Category	2 (8.7%)	1 (14.3%)	3 (10.0%)
		No Change	17 (73.9%)	5 (71.4%)	22 (73.3%)
		Improved by ≥1 Categories	3 (13.0%)	1 (14.3%)	4 (13.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (5.0%)	0 (0.0%)	1 (3.7%)
		Worsened by 1 Category	1 (5.0%)	1 (14.3%)	2 (7.4%)
		No Change	15 (75.0%)	6 (85.7%)	21 (77.8%)
		Improved by ≥1 Categories	3 (15.0%)	0 (0.0%)	3 (11.1%)
	C19D1		N=17	N=5	N=22
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.9%)	1 (20.0%)	2 (9.1%)
		No Change	13 (76.5%)	4 (80.0%)	17 (77.3%)
		Improved by ≥1 Categories	3 (17.6%)	0 (0.0%)	3 (13.6%)
	C20D1		N=18	N=4	N=22
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.6%)	0 (0.0%)	1 (4.5%)
		No Change	14 (77.8%)	3 (75.0%)	17 (77.3%)
		Improved by ≥1 Categories	3 (16.7%)	1 (25.0%)	4 (18.2%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.9%)	1 (25.0%)	2 (9.5%)
		No Change	13 (76.5%)	2 (50.0%)	15 (71.4%)
		Improved by ≥1 Categories	3 (17.6%)	1 (25.0%)	4 (19.0%)
	C22D1		N=14	N=3	N=17
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	14 (100.0%)	3 (100.0%)	17 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (8.3%)
		No Change	8 (88.9%)	3 (100.0%)	11 (91.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	1 (11.1%)	0 (0.0%)	1 (9.1%)
		Worsened by 2 Categories	1 (11.1%)	0 (0.0%)	1 (9.1%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (9.1%)
		No Change	6 (66.7%)	2 (100.0%)	8 (72.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=7	N=0	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (NE)	1 (14.3%)
		No Change	6 (85.7%)	0 (NE)	6 (85.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=5	N=1	N=6
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (100.0%)	1 (100.0%)	6 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=1	N=1	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (50.0%)
		No Change	1 (100.0%)	0 (0.0%)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	1 (100.0%)	2 (66.7%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C36D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=115	N=116	N=231
		Worsened by ≥3 Categories	5 (4.3%)	10 (8.6%)	15 (6.5%)
		Worsened by 2 Categories	6 (5.2%)	5 (4.3%)	11 (4.8%)
		Worsened by 1 Category	17 (14.8%)	15 (12.9%)	32 (13.9%)
		No Change	71 (61.7%)	64 (55.2%)	135 (58.4%)
		Improved by ≥1 Categories	16 (13.9%)	22 (19.0%)	38 (16.5%)
	Long Term Follow-up		N=13	N=9	N=22
		Worsened by ≥3 Categories	0 (0.0%)	2 (22.2%)	2 (9.1%)
		Worsened by 2 Categories	0 (0.0%)	1 (11.1%)	1 (4.5%)
		Worsened by 1 Category	3 (23.1%)	0 (0.0%)	3 (13.6%)
		No Change	8 (61.5%)	5 (55.6%)	13 (59.1%)
		Improved by ≥1 Categories	2 (15.4%)	1 (11.1%)	3 (13.6%)
Nausea Frequency	C2D1		N=150	N=143	N=293
		Worsened by ≥3 Categories	0 (0.0%)	3 (2.1%)	3 (1.0%)
		Worsened by 2 Categories	17 (11.3%)	13 (9.1%)	30 (10.2%)
		Worsened by 1 Category	37 (24.7%)	26 (18.2%)	63 (21.5%)
		No Change	80 (53.3%)	81 (56.6%)	161 (54.9%)
		Improved by ≥1 Categories	16 (10.7%)	20 (14.0%)	36 (12.3%)
	C3D1		N=115	N=101	N=216
		Worsened by ≥3 Categories	2 (1.7%)	3 (3.0%)	5 (2.3%)
		Worsened by 2 Categories	11 (9.6%)	8 (7.9%)	19 (8.8%)
		Worsened by 1 Category	23 (20.0%)	8 (7.9%)	31 (14.4%)
		No Change	65 (56.5%)	63 (62.4%)	128 (59.3%)
		Improved by ≥1 Categories	14 (12.2%)	19 (18.8%)	33 (15.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=107	N=93	N=200
		Worsened by ≥3 Categories	1 (0.9%)	0 (0.0%)	1 (0.5%)
		Worsened by 2 Categories	8 (7.5%)	4 (4.3%)	12 (6.0%)
		Worsened by 1 Category	22 (20.6%)	10 (10.8%)	32 (16.0%)
		No Change	58 (54.2%)	57 (61.3%)	115 (57.5%)
		Improved by ≥1 Categories	18 (16.8%)	22 (23.7%)	40 (20.0%)
	C5D1		N=92	N=80	N=172
		Worsened by ≥3 Categories	1 (1.1%)	0 (0.0%)	1 (0.6%)
		Worsened by 2 Categories	7 (7.6%)	3 (3.8%)	10 (5.8%)
		Worsened by 1 Category	10 (10.9%)	12 (15.0%)	22 (12.8%)
		No Change	57 (62.0%)	52 (65.0%)	109 (63.4%)
		Improved by ≥1 Categories	17 (18.5%)	13 (16.3%)	30 (17.4%)
	C6D1		N=90	N=71	N=161
		Worsened by ≥3 Categories	0 (0.0%)	1 (1.4%)	1 (0.6%)
		Worsened by 2 Categories	8 (8.9%)	3 (4.2%)	11 (6.8%)
		Worsened by 1 Category	10 (11.1%)	10 (14.1%)	20 (12.4%)
		No Change	59 (65.6%)	41 (57.7%)	100 (62.1%)
		Improved by ≥1 Categories	13 (14.4%)	16 (22.5%)	29 (18.0%)
	C7D1		N=75	N=54	N=129
		Worsened by ≥3 Categories	1 (1.3%)	0 (0.0%)	1 (0.8%)
		Worsened by 2 Categories	5 (6.7%)	0 (0.0%)	5 (3.9%)
		Worsened by 1 Category	9 (12.0%)	5 (9.3%)	14 (10.9%)
		No Change	45 (60.0%)	38 (70.4%)	83 (64.3%)
		Improved by ≥1 Categories	15 (20.0%)	11 (20.4%)	26 (20.2%)
	C8D1		N=70	N=50	N=120
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (1.4%)	1 (2.0%)	2 (1.7%)
		Worsened by 1 Category	12 (17.1%)	5 (10.0%)	17 (14.2%)
		No Change	42 (60.0%)	33 (66.0%)	75 (62.5%)
		Improved by ≥1 Categories	15 (21.4%)	11 (22.0%)	26 (21.7%)
	C9D1		N=57	N=41	N=98
		Worsened by ≥3 Categories	1 (1.8%)	0 (0.0%)	1 (1.0%)
		Worsened by 2 Categories	2 (3.5%)	0 (0.0%)	2 (2.0%)
		Worsened by 1 Category	7 (12.3%)	3 (7.3%)	10 (10.2%)
		No Change	36 (63.2%)	32 (78.0%)	68 (69.4%)
		Improved by ≥1 Categories	11 (19.3%)	6 (14.6%)	17 (17.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=50	N=30	N=80
		Worsened by ≥3 Categories	1 (2.0%)	0 (0.0%)	1 (1.3%)
		Worsened by 2 Categories	2 (4.0%)	1 (3.3%)	3 (3.8%)
		Worsened by 1 Category	5 (10.0%)	3 (10.0%)	8 (10.0%)
		No Change	33 (66.0%)	19 (63.3%)	52 (65.0%)
		Improved by ≥1 Categories	9 (18.0%)	7 (23.3%)	16 (20.0%)
	C11D1		N=43	N=23	N=66
		Worsened by ≥3 Categories	1 (2.3%)	0 (0.0%)	1 (1.5%)
		Worsened by 2 Categories	2 (4.7%)	0 (0.0%)	2 (3.0%)
		Worsened by 1 Category	3 (7.0%)	4 (17.4%)	7 (10.6%)
		No Change	32 (74.4%)	15 (65.2%)	47 (71.2%)
		Improved by ≥1 Categories	5 (11.6%)	4 (17.4%)	9 (13.6%)
	C12D1		N=39	N=19	N=58
		Worsened by ≥3 Categories	1 (2.6%)	0 (0.0%)	1 (1.7%)
		Worsened by 2 Categories	2 (5.1%)	1 (5.3%)	3 (5.2%)
		Worsened by 1 Category	7 (17.9%)	0 (0.0%)	7 (12.1%)
		No Change	23 (59.0%)	14 (73.7%)	37 (63.8%)
		Improved by ≥1 Categories	6 (15.4%)	4 (21.1%)	10 (17.2%)
	C13D1		N=31	N=14	N=45
		Worsened by ≥3 Categories	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Worsened by 2 Categories	4 (12.9%)	1 (7.1%)	5 (11.1%)
		Worsened by 1 Category	3 (9.7%)	2 (14.3%)	5 (11.1%)
		No Change	19 (61.3%)	10 (71.4%)	29 (64.4%)
		Improved by ≥1 Categories	4 (12.9%)	1 (7.1%)	5 (11.1%)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (9.7%)	2 (16.7%)	5 (11.6%)
		Worsened by 1 Category	4 (12.9%)	2 (16.7%)	6 (14.0%)
		No Change	20 (64.5%)	8 (66.7%)	28 (65.1%)
		Improved by ≥1 Categories	4 (12.9%)	0 (0.0%)	4 (9.3%)
	C15D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (7.7%)	0 (0.0%)	2 (5.1%)
		Worsened by 1 Category	1 (3.8%)	2 (15.4%)	3 (7.7%)
		No Change	17 (65.4%)	10 (76.9%)	27 (69.2%)
		Improved by ≥1 Categories	6 (23.1%)	1 (7.7%)	7 (17.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (10.0%)	1 (2.8%)
		Worsened by 1 Category	6 (23.1%)	2 (20.0%)	8 (22.2%)
		No Change	17 (65.4%)	6 (60.0%)	23 (63.9%)
		Improved by ≥1 Categories	3 (11.5%)	1 (10.0%)	4 (11.1%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.2%)	0 (0.0%)	1 (3.2%)
		Worsened by 1 Category	3 (12.5%)	0 (0.0%)	3 (9.7%)
		No Change	18 (75.0%)	7 (100.0%)	25 (80.6%)
		Improved by ≥1 Categories	2 (8.3%)	0 (0.0%)	2 (6.5%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (14.3%)	1 (3.7%)
		Worsened by 1 Category	4 (20.0%)	0 (0.0%)	4 (14.8%)
		No Change	13 (65.0%)	5 (71.4%)	18 (66.7%)
		Improved by ≥1 Categories	3 (15.0%)	1 (14.3%)	4 (14.8%)
	C19D1		N=18	N=6	N=24
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.6%)	1 (16.7%)	2 (8.3%)
		No Change	13 (72.2%)	5 (83.3%)	18 (75.0%)
		Improved by ≥1 Categories	4 (22.2%)	0 (0.0%)	4 (16.7%)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.3%)	0 (0.0%)	1 (4.3%)
		No Change	15 (78.9%)	4 (100.0%)	19 (82.6%)
		Improved by ≥1 Categories	3 (15.8%)	0 (0.0%)	3 (13.0%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (25.0%)	1 (4.8%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	13 (76.5%)	3 (75.0%)	16 (76.2%)
		Improved by ≥1 Categories	4 (23.5%)	0 (0.0%)	4 (19.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
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Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (6.7%)	1 (33.3%)	2 (11.1%)
		No Change	11 (73.3%)	2 (66.7%)	13 (72.2%)
		Improved by ≥1 Categories	3 (20.0%)	0 (0.0%)	3 (16.7%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (11.1%)	0 (0.0%)	1 (8.3%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	8 (88.9%)	3 (100.0%)	11 (91.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (33.3%)	1 (50.0%)	4 (36.4%)
		No Change	6 (66.7%)	1 (50.0%)	7 (63.6%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	1 (12.5%)	0 (NE)	1 (12.5%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	6 (75.0%)	0 (NE)	6 (75.0%)
		Improved by ≥1 Categories	1 (12.5%)	0 (NE)	1 (12.5%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (100.0%)	1 (100.0%)	7 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (NE)	1 (33.3%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=124	N=124	N=248
		Worsened by ≥3 Categories	0 (0.0%)	3 (2.4%)	3 (1.2%)
		Worsened by 2 Categories	11 (8.9%)	4 (3.2%)	15 (6.0%)
		Worsened by 1 Category	21 (16.9%)	22 (17.7%)	43 (17.3%)
		No Change	68 (54.8%)	74 (59.7%)	142 (57.3%)
		Improved by ≥1 Categories	24 (19.4%)	21 (16.9%)	45 (18.1%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 2 Categories	0 (0.0%)	2 (22.2%)	2 (8.7%)
		Worsened by 1 Category	1 (7.1%)	1 (11.1%)	2 (8.7%)
		No Change	12 (85.7%)	2 (22.2%)	14 (60.9%)
		Improved by ≥1 Categories	1 (7.1%)	3 (33.3%)	4 (17.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Nausea Severity	C2D1		N=143	N=129	N=272
		Worsened by ≥3 Categories	2 (1.4%)	0 (0.0%)	2 (0.7%)
		Worsened by 2 Categories	8 (5.6%)	10 (7.8%)	18 (6.6%)
		Worsened by 1 Category	33 (23.1%)	22 (17.1%)	55 (20.2%)
		No Change	85 (59.4%)	80 (62.0%)	165 (60.7%)
		Improved by ≥1 Categories	15 (10.5%)	17 (13.2%)	32 (11.8%)
	C3D1		N=111	N=93	N=204
		Worsened by ≥3 Categories	2 (1.8%)	2 (2.2%)	4 (2.0%)
		Worsened by 2 Categories	4 (3.6%)	4 (4.3%)	8 (3.9%)
		Worsened by 1 Category	21 (18.9%)	12 (12.9%)	33 (16.2%)
		No Change	71 (64.0%)	59 (63.4%)	130 (63.7%)
		Improved by ≥1 Categories	13 (11.7%)	16 (17.2%)	29 (14.2%)
	C4D1		N=98	N=89	N=187
		Worsened by ≥3 Categories	2 (2.0%)	2 (2.2%)	4 (2.1%)
		Worsened by 2 Categories	4 (4.1%)	4 (4.5%)	8 (4.3%)
		Worsened by 1 Category	21 (21.4%)	4 (4.5%)	25 (13.4%)
		No Change	56 (57.1%)	63 (70.8%)	119 (63.6%)
		Improved by ≥1 Categories	15 (15.3%)	16 (18.0%)	31 (16.6%)
	C5D1		N=87	N=71	N=158
		Worsened by ≥3 Categories	1 (1.1%)	0 (0.0%)	1 (0.6%)
		Worsened by 2 Categories	4 (4.6%)	0 (0.0%)	4 (2.5%)
		Worsened by 1 Category	13 (14.9%)	12 (16.9%)	25 (15.8%)
		No Change	56 (64.4%)	44 (62.0%)	100 (63.3%)
		Improved by ≥1 Categories	13 (14.9%)	15 (21.1%)	28 (17.7%)
	C6D1		N=80	N=64	N=144
		Worsened by ≥3 Categories	0 (0.0%)	1 (1.6%)	1 (0.7%)
		Worsened by 2 Categories	2 (2.5%)	0 (0.0%)	2 (1.4%)
		Worsened by 1 Category	14 (17.5%)	8 (12.5%)	22 (15.3%)
		No Change	54 (67.5%)	38 (59.4%)	92 (63.9%)
		Improved by ≥1 Categories	10 (12.5%)	17 (26.6%)	27 (18.8%)
	C7D1		N=69	N=47	N=116
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (5.8%)	0 (0.0%)	4 (3.4%)
		Worsened by 1 Category	10 (14.5%)	2 (4.3%)	12 (10.3%)
		No Change	41 (59.4%)	36 (76.6%)	77 (66.4%)
		Improved by ≥1 Categories	14 (20.3%)	9 (19.1%)	23 (19.8%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C8D1		N=64	N=43	N=107
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (1.6%)	1 (2.3%)	2 (1.9%)
		Worsened by 1 Category	10 (15.6%)	4 (9.3%)	14 (13.1%)
		No Change	42 (65.6%)	27 (62.8%)	69 (64.5%)
		Improved by ≥1 Categories	11 (17.2%)	11 (25.6%)	22 (20.6%)
	C9D1		N=52	N=38	N=90
		Worsened by ≥3 Categories	1 (1.9%)	0 (0.0%)	1 (1.1%)
		Worsened by 2 Categories	1 (1.9%)	1 (2.6%)	2 (2.2%)
		Worsened by 1 Category	6 (11.5%)	2 (5.3%)	8 (8.9%)
		No Change	35 (67.3%)	29 (76.3%)	64 (71.1%)
		Improved by ≥1 Categories	9 (17.3%)	6 (15.8%)	15 (16.7%)
	C10D1		N=47	N=28	N=75
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.1%)	0 (0.0%)	1 (1.3%)
		Worsened by 1 Category	6 (12.8%)	3 (10.7%)	9 (12.0%)
		No Change	34 (72.3%)	20 (71.4%)	54 (72.0%)
		Improved by ≥1 Categories	6 (12.8%)	5 (17.9%)	11 (14.7%)
	C11D1		N=41	N=23	N=64
		Worsened by ≥3 Categories	1 (2.4%)	0 (0.0%)	1 (1.6%)
		Worsened by 2 Categories	1 (2.4%)	0 (0.0%)	1 (1.6%)
		Worsened by 1 Category	4 (9.8%)	2 (8.7%)	6 (9.4%)
		No Change	31 (75.6%)	17 (73.9%)	48 (75.0%)
		Improved by ≥1 Categories	4 (9.8%)	4 (17.4%)	8 (12.5%)
	C12D1		N=36	N=18	N=54
		Worsened by ≥3 Categories	1 (2.8%)	0 (0.0%)	1 (1.9%)
		Worsened by 2 Categories	1 (2.8%)	1 (5.6%)	2 (3.7%)
		Worsened by 1 Category	4 (11.1%)	0 (0.0%)	4 (7.4%)
		No Change	26 (72.2%)	13 (72.2%)	39 (72.2%)
		Improved by ≥1 Categories	4 (11.1%)	4 (22.2%)	8 (14.8%)
	C13D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	1 (3.8%)	0 (0.0%)	1 (2.6%)
		Worsened by 2 Categories	2 (7.7%)	0 (0.0%)	2 (5.1%)
		Worsened by 1 Category	3 (11.5%)	1 (7.7%)	4 (10.3%)
		No Change	18 (69.2%)	11 (84.6%)	29 (74.4%)
		Improved by ≥1 Categories	2 (7.7%)	1 (7.7%)	3 (7.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C14D1		N=30	N=12	N=42
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (3.3%)	0 (0.0%)	1 (2.4%)
		Worsened by 1 Category	3 (10.0%)	2 (16.7%)	5 (11.9%)
		No Change	23 (76.7%)	10 (83.3%)	33 (78.6%)
		Improved by ≥1 Categories	3 (10.0%)	0 (0.0%)	3 (7.1%)
	C15D1		N=25	N=12	N=37
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.0%)	0 (0.0%)	1 (2.7%)
		Worsened by 1 Category	2 (8.0%)	1 (8.3%)	3 (8.1%)
		No Change	19 (76.0%)	9 (75.0%)	28 (75.7%)
		Improved by ≥1 Categories	3 (12.0%)	2 (16.7%)	5 (13.5%)
	C16D1		N=25	N=10	N=35
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (10.0%)	1 (2.9%)
		Worsened by 1 Category	5 (20.0%)	2 (20.0%)	7 (20.0%)
		No Change	17 (68.0%)	6 (60.0%)	23 (65.7%)
		Improved by ≥1 Categories	3 (12.0%)	1 (10.0%)	4 (11.4%)
	C17D1		N=23	N=7	N=30
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.3%)	0 (0.0%)	1 (3.3%)
		Worsened by 1 Category	3 (13.0%)	0 (0.0%)	3 (10.0%)
		No Change	16 (69.6%)	6 (85.7%)	22 (73.3%)
		Improved by ≥1 Categories	3 (13.0%)	1 (14.3%)	4 (13.3%)
	C18D1		N=19	N=7	N=26
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (5.3%)	0 (0.0%)	1 (3.8%)
		Worsened by 1 Category	1 (5.3%)	1 (14.3%)	2 (7.7%)
		No Change	15 (78.9%)	5 (71.4%)	20 (76.9%)
		Improved by ≥1 Categories	2 (10.5%)	1 (14.3%)	3 (11.5%)
	C19D1		N=19	N=5	N=24
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.3%)	0 (0.0%)	1 (4.2%)
		No Change	15 (78.9%)	5 (100.0%)	20 (83.3%)
		Improved by ≥1 Categories	3 (15.8%)	0 (0.0%)	3 (12.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C20D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.9%)	0 (0.0%)	1 (4.8%)
		No Change	14 (82.4%)	3 (75.0%)	17 (81.0%)
		Improved by ≥1 Categories	2 (11.8%)	1 (25.0%)	3 (14.3%)
	C21D1		N=16	N=4	N=20
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (25.0%)	1 (5.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	13 (81.3%)	3 (75.0%)	16 (80.0%)
		Improved by ≥1 Categories	3 (18.8%)	0 (0.0%)	3 (15.0%)
	C22D1		N=14	N=3	N=17
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (7.1%)	0 (0.0%)	1 (5.9%)
		No Change	12 (85.7%)	3 (100.0%)	15 (88.2%)
		Improved by ≥1 Categories	1 (7.1%)	0 (0.0%)	1 (5.9%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	1 (11.1%)	0 (0.0%)	1 (8.3%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	7 (77.8%)	3 (100.0%)	10 (83.3%)
		Improved by ≥1 Categories	1 (11.1%)	0 (0.0%)	1 (8.3%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	1 (50.0%)	2 (18.2%)
		No Change	8 (88.9%)	1 (50.0%)	9 (81.8%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=7	N=0	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (NE)	1 (14.3%)
		No Change	5 (71.4%)	0 (NE)	5 (71.4%)
		Improved by ≥1 Categories	1 (14.3%)	0 (NE)	1 (14.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=5	N=1	N=6
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (100.0%)	1 (100.0%)	6 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=1	N=1	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	1 (100.0%)	1 (100.0%)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	EOT		N=110	N=112	N=222
		Worsened by ≥3 Categories	2 (1.8%)	3 (2.7%)	5 (2.3%)
		Worsened by 2 Categories	4 (3.6%)	4 (3.6%)	8 (3.6%)
		Worsened by 1 Category	27 (24.5%)	20 (17.9%)	47 (21.2%)
		No Change	59 (53.6%)	66 (58.9%)	125 (56.3%)
		Improved by ≥1 Categories	18 (16.4%)	19 (17.0%)	37 (16.7%)
	Long Term		N=13	N=8	N=21
	Follow-up	Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (12.5%)	1 (4.8%)
		Worsened by 1 Category	2 (15.4%)	2 (25.0%)	4 (19.0%)
		No Change	9 (69.2%)	2 (25.0%)	11 (52.4%)
		Improved by ≥1 Categories	2 (15.4%)	3 (37.5%)	5 (23.8%)
Vomiting Frequency	C2D1		N=150	N=143	N=293
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (2.7%)	4 (2.8%)	8 (2.7%)
		Worsened by 1 Category	4 (2.7%)	9 (6.3%)	13 (4.4%)
		No Change	133 (88.7%)	120 (83.9%)	253 (86.3%)
		Improved by ≥1 Categories	9 (6.0%)	10 (7.0%)	19 (6.5%)
	C3D1		N=116	N=102	N=218
		Worsened by ≥3 Categories	1 (0.9%)	0 (0.0%)	1 (0.5%)
		Worsened by 2 Categories	1 (0.9%)	2 (2.0%)	3 (1.4%)
		Worsened by 1 Category	9 (7.8%)	3 (2.9%)	12 (5.5%)
		No Change	97 (83.6%)	89 (87.3%)	186 (85.3%)
		Improved by ≥1 Categories	8 (6.9%)	8 (7.8%)	16 (7.3%)
	C4D1		N=107	N=93	N=200
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (2.8%)	2 (2.2%)	5 (2.5%)
		Worsened by 1 Category	3 (2.8%)	4 (4.3%)	7 (3.5%)
		No Change	90 (84.1%)	78 (83.9%)	168 (84.0%)
		Improved by ≥1 Categories	11 (10.3%)	9 (9.7%)	20 (10.0%)
	C5D1		N=93	N=80	N=173
		Worsened by ≥3 Categories	1 (1.1%)	0 (0.0%)	1 (0.6%)
		Worsened by 2 Categories	1 (1.1%)	0 (0.0%)	1 (0.6%)
		Worsened by 1 Category	3 (3.2%)	3 (3.8%)	6 (3.5%)
		No Change	80 (86.0%)	71 (88.8%)	151 (87.3%)
		Improved by ≥1 Categories	8 (8.6%)	6 (7.5%)	14 (8.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C6D1		N=90	N=71	N=161
		Worsened by ≥3 Categories	1 (1.1%)	0 (0.0%)	1 (0.6%)
		Worsened by 2 Categories	2 (2.2%)	2 (2.8%)	4 (2.5%)
		Worsened by 1 Category	3 (3.3%)	2 (2.8%)	5 (3.1%)
		No Change	77 (85.6%)	59 (83.1%)	136 (84.5%)
		Improved by ≥1 Categories	7 (7.8%)	8 (11.3%)	15 (9.3%)
	C7D1		N=75	N=53	N=128
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (1.3%)	1 (1.9%)	2 (1.6%)
		No Change	68 (90.7%)	48 (90.6%)	116 (90.6%)
		Improved by ≥1 Categories	6 (8.0%)	4 (7.5%)	10 (7.8%)
	C8D1		N=70	N=50	N=120
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (2.0%)	1 (0.8%)
		No Change	65 (92.9%)	44 (88.0%)	109 (90.8%)
		Improved by ≥1 Categories	5 (7.1%)	5 (10.0%)	10 (8.3%)
	C9D1		N=57	N=41	N=98
		Worsened by ≥3 Categories	1 (1.8%)	0 (0.0%)	1 (1.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (5.3%)	0 (0.0%)	3 (3.1%)
		No Change	50 (87.7%)	36 (87.8%)	86 (87.8%)
		Improved by ≥1 Categories	3 (5.3%)	5 (12.2%)	8 (8.2%)
	C10D1		N=50	N=30	N=80
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (2.0%)	1 (3.3%)	2 (2.5%)
		No Change	45 (90.0%)	26 (86.7%)	71 (88.8%)
		Improved by ≥1 Categories	4 (8.0%)	3 (10.0%)	7 (8.8%)
	C11D1		N=43	N=23	N=66
		Worsened by ≥3 Categories	1 (2.3%)	0 (0.0%)	1 (1.5%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	41 (95.3%)	21 (91.3%)	62 (93.9%)
		Improved by ≥1 Categories	1 (2.3%)	2 (8.7%)	3 (4.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C12D1		N=39	N=19	N=58
		Worsened by ≥3 Categories	1 (2.6%)	0 (0.0%)	1 (1.7%)
		Worsened by 2 Categories	1 (2.6%)	1 (5.3%)	2 (3.4%)
		Worsened by 1 Category	2 (5.1%)	0 (0.0%)	2 (3.4%)
		No Change	34 (87.2%)	17 (89.5%)	51 (87.9%)
		Improved by ≥1 Categories	1 (2.6%)	1 (5.3%)	2 (3.4%)
	C13D1		N=31	N=14	N=45
		Worsened by ≥3 Categories	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Worsened by 2 Categories	1 (3.2%)	0 (0.0%)	1 (2.2%)
		Worsened by 1 Category	1 (3.2%)	0 (0.0%)	1 (2.2%)
		No Change	27 (87.1%)	12 (85.7%)	39 (86.7%)
		Improved by ≥1 Categories	1 (3.2%)	2 (14.3%)	3 (6.7%)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (6.5%)	0 (0.0%)	2 (4.7%)
		No Change	29 (93.5%)	11 (91.7%)	40 (93.0%)
		Improved by ≥1 Categories	0 (0.0%)	1 (8.3%)	1 (2.3%)
	C15D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (3.8%)	0 (0.0%)	1 (2.6%)
		No Change	25 (96.2%)	11 (84.6%)	36 (92.3%)
		Improved by ≥1 Categories	0 (0.0%)	2 (15.4%)	2 (5.1%)
	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (11.5%)	0 (0.0%)	3 (8.3%)
		No Change	23 (88.5%)	8 (80.0%)	31 (86.1%)
		Improved by ≥1 Categories	0 (0.0%)	2 (20.0%)	2 (5.6%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (8.3%)	0 (0.0%)	2 (6.5%)
		No Change	22 (91.7%)	6 (85.7%)	28 (90.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (14.3%)	1 (3.2%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	20 (100.0%)	6 (85.7%)	26 (96.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (14.3%)	1 (3.7%)
	C19D1		N=18	N=6	N=24
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.6%)	0 (0.0%)	1 (4.2%)
		No Change	17 (94.4%)	5 (83.3%)	22 (91.7%)
		Improved by ≥1 Categories	0 (0.0%)	1 (16.7%)	1 (4.2%)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.3%)	0 (0.0%)	1 (4.3%)
		No Change	18 (94.7%)	3 (75.0%)	21 (91.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (25.0%)	1 (4.3%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	17 (100.0%)	3 (75.0%)	20 (95.2%)
		Improved by ≥1 Categories	0 (0.0%)	1 (25.0%)	1 (4.8%)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	15 (100.0%)	2 (66.7%)	17 (94.4%)
		Improved by ≥1 Categories	0 (0.0%)	1 (33.3%)	1 (5.6%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	1 (11.1%)	0 (0.0%)	1 (8.3%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	8 (88.9%)	2 (66.7%)	10 (83.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (33.3%)	1 (8.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (11.1%)	0 (0.0%)	1 (9.1%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	8 (88.9%)	1 (50.0%)	9 (81.8%)
		Improved by ≥1 Categories	0 (0.0%)	1 (50.0%)	1 (9.1%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	8 (100.0%)	0 (NE)	8 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (100.0%)	1 (100.0%)	7 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (NE)	1 (33.3%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=124	N=125	N=249
		Worsened by ≥3 Categories	1 (0.8%)	2 (1.6%)	3 (1.2%)
		Worsened by 2 Categories	9 (7.3%)	3 (2.4%)	12 (4.8%)
		Worsened by 1 Category	5 (4.0%)	9 (7.2%)	14 (5.6%)
		No Change	98 (79.0%)	103 (82.4%)	201 (80.7%)
		Improved by ≥1 Categories	11 (8.9%)	8 (6.4%)	19 (7.6%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 2 Categories	1 (7.1%)	0 (0.0%)	1 (4.3%)
		Worsened by 1 Category	0 (0.0%)	1 (11.1%)	1 (4.3%)
		No Change	11 (78.6%)	7 (77.8%)	18 (78.3%)
		Improved by ≥1 Categories	2 (14.3%)	0 (0.0%)	2 (8.7%)
Vomiting Severity	C2D1		N=143	N=130	N=273
		Worsened by ≥3 Categories	2 (1.4%)	1 (0.8%)	3 (1.1%)
		Worsened by 2 Categories	1 (0.7%)	3 (2.3%)	4 (1.5%)
		Worsened by 1 Category	8 (5.6%)	7 (5.4%)	15 (5.5%)
		No Change	124 (86.7%)	110 (84.6%)	234 (85.7%)
		Improved by ≥1 Categories	8 (5.6%)	9 (6.9%)	17 (6.2%)
	C3D1		N=111	N=93	N=204
		Worsened by ≥3 Categories	3 (2.7%)	1 (1.1%)	4 (2.0%)
		Worsened by 2 Categories	2 (1.8%)	1 (1.1%)	3 (1.5%)
		Worsened by 1 Category	4 (3.6%)	4 (4.3%)	8 (3.9%)
		No Change	95 (85.6%)	78 (83.9%)	173 (84.8%)
		Improved by ≥1 Categories	7 (6.3%)	9 (9.7%)	16 (7.8%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=98	N=89	N=187
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (1.0%)	2 (2.2%)	3 (1.6%)
		Worsened by 1 Category	5 (5.1%)	5 (5.6%)	10 (5.3%)
		No Change	83 (84.7%)	73 (82.0%)	156 (83.4%)
		Improved by ≥1 Categories	9 (9.2%)	9 (10.1%)	18 (9.6%)
	C5D1		N=86	N=72	N=158
		Worsened by ≥3 Categories	1 (1.2%)	0 (0.0%)	1 (0.6%)
		Worsened by 2 Categories	1 (1.2%)	0 (0.0%)	1 (0.6%)
		Worsened by 1 Category	3 (3.5%)	5 (6.9%)	8 (5.1%)
		No Change	74 (86.0%)	61 (84.7%)	135 (85.4%)
		Improved by ≥1 Categories	7 (8.1%)	6 (8.3%)	13 (8.2%)
	C6D1		N=79	N=63	N=142
		Worsened by ≥3 Categories	0 (0.0%)	1 (1.6%)	1 (0.7%)
		Worsened by 2 Categories	2 (2.5%)	0 (0.0%)	2 (1.4%)
		Worsened by 1 Category	3 (3.8%)	2 (3.2%)	5 (3.5%)
		No Change	68 (86.1%)	52 (82.5%)	120 (84.5%)
		Improved by ≥1 Categories	6 (7.6%)	8 (12.7%)	14 (9.9%)
	C7D1		N=67	N=46	N=113
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (2.2%)	1 (0.9%)
		No Change	59 (88.1%)	40 (87.0%)	99 (87.6%)
		Improved by ≥1 Categories	8 (11.9%)	5 (10.9%)	13 (11.5%)
	C8D1		N=63	N=43	N=106
		Worsened by ≥3 Categories	0 (0.0%)	1 (2.3%)	1 (0.9%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	58 (92.1%)	37 (86.0%)	95 (89.6%)
		Improved by ≥1 Categories	5 (7.9%)	5 (11.6%)	10 (9.4%)
	C9D1		N=50	N=38	N=88
		Worsened by ≥3 Categories	1 (2.0%)	0 (0.0%)	1 (1.1%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (6.0%)	0 (0.0%)	3 (3.4%)
		No Change	42 (84.0%)	33 (86.8%)	75 (85.2%)
		Improved by ≥1 Categories	4 (8.0%)	5 (13.2%)	9 (10.2%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=45	N=28	N=73
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (2.2%)	1 (3.6%)	2 (2.7%)
		No Change	42 (93.3%)	25 (89.3%)	67 (91.8%)
		Improved by ≥1 Categories	2 (4.4%)	2 (7.1%)	4 (5.5%)
	C11D1		N=40	N=22	N=62
		Worsened by ≥3 Categories	1 (2.5%)	0 (0.0%)	1 (1.6%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	38 (95.0%)	20 (90.9%)	58 (93.5%)
		Improved by ≥1 Categories	1 (2.5%)	2 (9.1%)	3 (4.8%)
	C12D1		N=35	N=18	N=53
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.9%)	1 (5.6%)	2 (3.8%)
		Worsened by 1 Category	1 (2.9%)	0 (0.0%)	1 (1.9%)
		No Change	32 (91.4%)	16 (88.9%)	48 (90.6%)
		Improved by ≥1 Categories	1 (2.9%)	1 (5.6%)	2 (3.8%)
	C13D1		N=27	N=13	N=40
		Worsened by ≥3 Categories	2 (7.4%)	0 (0.0%)	2 (5.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	23 (85.2%)	11 (84.6%)	34 (85.0%)
		Improved by ≥1 Categories	2 (7.4%)	2 (15.4%)	4 (10.0%)
	C14D1		N=29	N=12	N=41
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (3.4%)	0 (0.0%)	1 (2.4%)
		No Change	27 (93.1%)	11 (91.7%)	38 (92.7%)
		Improved by ≥1 Categories	1 (3.4%)	1 (8.3%)	2 (4.9%)
	C15D1		N=24	N=11	N=35
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	24 (100.0%)	9 (81.8%)	33 (94.3%)
		Improved by ≥1 Categories	0 (0.0%)	2 (18.2%)	2 (5.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=24	N=10	N=34
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	4 (16.7%)	0 (0.0%)	4 (11.8%)
		No Change	19 (79.2%)	8 (80.0%)	27 (79.4%)
		Improved by ≥1 Categories	1 (4.2%)	2 (20.0%)	3 (8.8%)
	C17D1		N=23	N=7	N=30
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (4.3%)	0 (0.0%)	1 (3.3%)
		No Change	21 (91.3%)	6 (85.7%)	27 (90.0%)
		Improved by ≥1 Categories	1 (4.3%)	1 (14.3%)	2 (6.7%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.0%)	0 (0.0%)	1 (3.7%)
		No Change	19 (95.0%)	6 (85.7%)	25 (92.6%)
		Improved by ≥1 Categories	0 (0.0%)	1 (14.3%)	1 (3.7%)
	C19D1		N=19	N=5	N=24
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.3%)	0 (0.0%)	1 (4.2%)
		No Change	18 (94.7%)	4 (80.0%)	22 (91.7%)
		Improved by ≥1 Categories	0 (0.0%)	1 (20.0%)	1 (4.2%)
	C20D1		N=18	N=4	N=22
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.6%)	0 (0.0%)	1 (4.5%)
		No Change	17 (94.4%)	3 (75.0%)	20 (90.9%)
		Improved by ≥1 Categories	0 (0.0%)	1 (25.0%)	1 (4.5%)
	C21D1		N=16	N=4	N=20
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	16 (100.0%)	3 (75.0%)	19 (95.0%)
		Improved by ≥1 Categories	0 (0.0%)	1 (25.0%)	1 (5.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=14	N=3	N=17
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	14 (100.0%)	2 (66.7%)	16 (94.1%)
		Improved by ≥1 Categories	0 (0.0%)	1 (33.3%)	1 (5.9%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	1 (11.1%)	0 (0.0%)	1 (8.3%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	8 (88.9%)	2 (66.7%)	10 (83.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (33.3%)	1 (8.3%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	1 (11.1%)	0 (0.0%)	1 (9.1%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (9.1%)
		No Change	7 (77.8%)	1 (50.0%)	8 (72.7%)
		Improved by ≥1 Categories	0 (0.0%)	1 (50.0%)	1 (9.1%)
	C25D1		N=7	N=0	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	7 (100.0%)	0 (NE)	7 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	7 (100.0%)	1 (100.0%)	8 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=5	N=1	N=6
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (100.0%)	1 (100.0%)	6 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=1	N=1	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	1 (100.0%)	1 (100.0%)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=108	N=110	N=218
		Worsened by ≥3 Categories	2 (1.9%)	2 (1.8%)	4 (1.8%)
		Worsened by 2 Categories	4 (3.7%)	4 (3.6%)	8 (3.7%)
		Worsened by 1 Category	6 (5.6%)	6 (5.5%)	12 (5.5%)
		No Change	87 (80.6%)	92 (83.6%)	179 (82.1%)
		Improved by ≥1 Categories	9 (8.3%)	6 (5.5%)	15 (6.9%)
	Long Term Follow-up		N=13	N=8	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (7.7%)	1 (12.5%)	2 (9.5%)
		No Change	10 (76.9%)	7 (87.5%)	17 (81.0%)
		Improved by ≥1 Categories	2 (15.4%)	0 (0.0%)	2 (9.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Constipation Severity	C2D1		N=150	N=143	N=293
		Worsened by ≥3 Categories	4 (2.7%)	3 (2.1%)	7 (2.4%)
		Worsened by 2 Categories	6 (4.0%)	7 (4.9%)	13 (4.4%)
		Worsened by 1 Category	26 (17.3%)	30 (21.0%)	56 (19.1%)
		No Change	88 (58.7%)	84 (58.7%)	172 (58.7%)
		Improved by ≥1 Categories	26 (17.3%)	19 (13.3%)	45 (15.4%)
	C3D1		N=116	N=102	N=218
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (3.4%)	4 (3.9%)	8 (3.7%)
		Worsened by 1 Category	22 (19.0%)	12 (11.8%)	34 (15.6%)
		No Change	61 (52.6%)	67 (65.7%)	128 (58.7%)
		Improved by ≥1 Categories	29 (25.0%)	19 (18.6%)	48 (22.0%)
	C4D1		N=107	N=93	N=200
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	6 (5.6%)	5 (5.4%)	11 (5.5%)
		Worsened by 1 Category	12 (11.2%)	9 (9.7%)	21 (10.5%)
		No Change	64 (59.8%)	58 (62.4%)	122 (61.0%)
		Improved by ≥1 Categories	25 (23.4%)	21 (22.6%)	46 (23.0%)
	C5D1		N=93	N=79	N=172
		Worsened by ≥3 Categories	2 (2.2%)	1 (1.3%)	3 (1.7%)
		Worsened by 2 Categories	2 (2.2%)	1 (1.3%)	3 (1.7%)
		Worsened by 1 Category	11 (11.8%)	13 (16.5%)	24 (14.0%)
		No Change	48 (51.6%)	47 (59.5%)	95 (55.2%)
		Improved by ≥1 Categories	30 (32.3%)	17 (21.5%)	47 (27.3%)
	C6D1		N=90	N=71	N=161
		Worsened by ≥3 Categories	1 (1.1%)	0 (0.0%)	1 (0.6%)
		Worsened by 2 Categories	3 (3.3%)	2 (2.8%)	5 (3.1%)
		Worsened by 1 Category	10 (11.1%)	11 (15.5%)	21 (13.0%)
		No Change	51 (56.7%)	42 (59.2%)	93 (57.8%)
		Improved by ≥1 Categories	25 (27.8%)	16 (22.5%)	41 (25.5%)
	C7D1		N=74	N=53	N=127
		Worsened by ≥3 Categories	1 (1.4%)	0 (0.0%)	1 (0.8%)
		Worsened by 2 Categories	3 (4.1%)	4 (7.5%)	7 (5.5%)
		Worsened by 1 Category	7 (9.5%)	6 (11.3%)	13 (10.2%)
		No Change	41 (55.4%)	34 (64.2%)	75 (59.1%)
		Improved by ≥1 Categories	22 (29.7%)	9 (17.0%)	31 (24.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C8D1		N=69	N=50	N=119
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (4.3%)	4 (8.0%)	7 (5.9%)
		Worsened by 1 Category	11 (15.9%)	10 (20.0%)	21 (17.6%)
		No Change	39 (56.5%)	26 (52.0%)	65 (54.6%)
		Improved by ≥1 Categories	16 (23.2%)	10 (20.0%)	26 (21.8%)
	C9D1		N=57	N=41	N=98
		Worsened by ≥3 Categories	1 (1.8%)	1 (2.4%)	2 (2.0%)
		Worsened by 2 Categories	1 (1.8%)	2 (4.9%)	3 (3.1%)
		Worsened by 1 Category	8 (14.0%)	4 (9.8%)	12 (12.2%)
		No Change	36 (63.2%)	26 (63.4%)	62 (63.3%)
		Improved by ≥1 Categories	11 (19.3%)	8 (19.5%)	19 (19.4%)
	C10D1		N=50	N=30	N=80
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	5 (10.0%)	3 (10.0%)	8 (10.0%)
		Worsened by 1 Category	10 (20.0%)	4 (13.3%)	14 (17.5%)
		No Change	28 (56.0%)	17 (56.7%)	45 (56.3%)
		Improved by ≥1 Categories	7 (14.0%)	6 (20.0%)	13 (16.3%)
	C11D1		N=43	N=23	N=66
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	5 (11.6%)	3 (13.0%)	8 (12.1%)
		Worsened by 1 Category	5 (11.6%)	2 (8.7%)	7 (10.6%)
		No Change	26 (60.5%)	14 (60.9%)	40 (60.6%)
		Improved by ≥1 Categories	7 (16.3%)	4 (17.4%)	11 (16.7%)
	C12D1		N=39	N=19	N=58
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (10.3%)	1 (5.3%)	5 (8.6%)
		Worsened by 1 Category	9 (23.1%)	3 (15.8%)	12 (20.7%)
		No Change	21 (53.8%)	9 (47.4%)	30 (51.7%)
		Improved by ≥1 Categories	5 (12.8%)	6 (31.6%)	11 (19.0%)
	C13D1		N=31	N=14	N=45
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	5 (16.1%)	2 (14.3%)	7 (15.6%)
		Worsened by 1 Category	7 (22.6%)	1 (7.1%)	8 (17.8%)
		No Change	14 (45.2%)	6 (42.9%)	20 (44.4%)
		Improved by ≥1 Categories	5 (16.1%)	5 (35.7%)	10 (22.2%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	2 (6.5%)	0 (0.0%)	2 (4.7%)
		Worsened by 2 Categories	5 (16.1%)	1 (8.3%)	6 (14.0%)
		Worsened by 1 Category	5 (16.1%)	2 (16.7%)	7 (16.3%)
		No Change	15 (48.4%)	6 (50.0%)	21 (48.8%)
		Improved by ≥1 Categories	4 (12.9%)	3 (25.0%)	7 (16.3%)
	C15D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	1 (3.8%)	0 (0.0%)	1 (2.6%)
		Worsened by 2 Categories	3 (11.5%)	0 (0.0%)	3 (7.7%)
		Worsened by 1 Category	5 (19.2%)	3 (23.1%)	8 (20.5%)
		No Change	14 (53.8%)	5 (38.5%)	19 (48.7%)
		Improved by ≥1 Categories	3 (11.5%)	5 (38.5%)	8 (20.5%)
	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (15.4%)	0 (0.0%)	4 (11.1%)
		Worsened by 1 Category	4 (15.4%)	4 (40.0%)	8 (22.2%)
		No Change	16 (61.5%)	3 (30.0%)	19 (52.8%)
		Improved by ≥1 Categories	2 (7.7%)	3 (30.0%)	5 (13.9%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (8.3%)	0 (0.0%)	2 (6.5%)
		Worsened by 1 Category	5 (20.8%)	1 (14.3%)	6 (19.4%)
		No Change	15 (62.5%)	4 (57.1%)	19 (61.3%)
		Improved by ≥1 Categories	2 (8.3%)	2 (28.6%)	4 (12.9%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	1 (5.0%)	0 (0.0%)	1 (3.7%)
		Worsened by 2 Categories	3 (15.0%)	0 (0.0%)	3 (11.1%)
		Worsened by 1 Category	5 (25.0%)	1 (14.3%)	6 (22.2%)
		No Change	10 (50.0%)	3 (42.9%)	13 (48.1%)
		Improved by ≥1 Categories	1 (5.0%)	3 (42.9%)	4 (14.8%)
	C19D1		N=19	N=6	N=25
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (10.5%)	0 (0.0%)	2 (8.0%)
		Worsened by 1 Category	8 (42.1%)	2 (33.3%)	10 (40.0%)
		No Change	9 (47.4%)	2 (33.3%)	11 (44.0%)
		Improved by ≥1 Categories	0 (0.0%)	2 (33.3%)	2 (8.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	5 (26.3%)	0 (0.0%)	5 (21.7%)
		No Change	13 (68.4%)	1 (25.0%)	14 (60.9%)
		Improved by ≥1 Categories	1 (5.3%)	3 (75.0%)	4 (17.4%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (17.6%)	0 (0.0%)	3 (14.3%)
		No Change	14 (82.4%)	2 (50.0%)	16 (76.2%)
		Improved by ≥1 Categories	0 (0.0%)	2 (50.0%)	2 (9.5%)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (13.3%)	0 (0.0%)	2 (11.1%)
		Worsened by 1 Category	2 (13.3%)	1 (33.3%)	3 (16.7%)
		No Change	10 (66.7%)	0 (0.0%)	10 (55.6%)
		Improved by ≥1 Categories	1 (6.7%)	2 (66.7%)	3 (16.7%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (22.2%)	0 (0.0%)	2 (16.7%)
		Worsened by 1 Category	0 (0.0%)	1 (33.3%)	1 (8.3%)
		No Change	7 (77.8%)	0 (0.0%)	7 (58.3%)
		Improved by ≥1 Categories	0 (0.0%)	2 (66.7%)	2 (16.7%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (22.2%)	0 (0.0%)	2 (18.2%)
		Worsened by 1 Category	2 (22.2%)	0 (0.0%)	2 (18.2%)
		No Change	5 (55.6%)	1 (50.0%)	6 (54.5%)
		Improved by ≥1 Categories	0 (0.0%)	1 (50.0%)	1 (9.1%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	1 (12.5%)	0 (NE)	1 (12.5%)
		Worsened by 1 Category	3 (37.5%)	0 (NE)	3 (37.5%)
		No Change	4 (50.0%)	0 (NE)	4 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	5 (71.4%)	0 (0.0%)	5 (62.5%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (12.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	4 (57.1%)	0 (0.0%)	4 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (12.5%)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (33.3%)	0 (0.0%)	2 (28.6%)
		No Change	4 (66.7%)	0 (0.0%)	4 (57.1%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (14.3%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	0 (0.0%)	4 (80.0%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (25.0%)	0 (0.0%)	1 (20.0%)
		No Change	3 (75.0%)	1 (100.0%)	4 (80.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (0.0%)	1 (33.3%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (33.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (NE)	1 (33.3%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (NE)	1 (33.3%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (NE)	1 (33.3%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
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Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	EOT		N=124	N=124	N=248
		Worsened by ≥3 Categories	3 (2.4%)	2 (1.6%)	5 (2.0%)
		Worsened by 2 Categories	9 (7.3%)	7 (5.6%)	16 (6.5%)
		Worsened by 1 Category	13 (10.5%)	20 (16.1%)	33 (13.3%)
		No Change	72 (58.1%)	68 (54.8%)	140 (56.5%)
		Improved by ≥1 Categories	27 (21.8%)	27 (21.8%)	54 (21.8%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 2 Categories	2 (14.3%)	2 (22.2%)	4 (17.4%)
		Worsened by 1 Category	2 (14.3%)	1 (11.1%)	3 (13.0%)
		No Change	9 (64.3%)	2 (22.2%)	11 (47.8%)
		Improved by ≥1 Categories	1 (7.1%)	3 (33.3%)	4 (17.4%)
Diarrhea Frequency	C2D1		N=149	N=142	N=291
		Worsened by ≥3 Categories	16 (10.7%)	1 (0.7%)	17 (5.8%)
		Worsened by 2 Categories	29 (19.5%)	8 (5.6%)	37 (12.7%)
		Worsened by 1 Category	22 (14.8%)	16 (11.3%)	38 (13.1%)
		No Change	71 (47.7%)	82 (57.7%)	153 (52.6%)
		Improved by ≥1 Categories	11 (7.4%)	35 (24.6%)	46 (15.8%)
	C3D1		N=116	N=100	N=216
		Worsened by ≥3 Categories	13 (11.2%)	1 (1.0%)	14 (6.5%)
		Worsened by 2 Categories	13 (11.2%)	9 (9.0%)	22 (10.2%)
		Worsened by 1 Category	21 (18.1%)	12 (12.0%)	33 (15.3%)
		No Change	60 (51.7%)	57 (57.0%)	117 (54.2%)
		Improved by ≥1 Categories	9 (7.8%)	21 (21.0%)	30 (13.9%)
	C4D1		N=106	N=93	N=199
		Worsened by ≥3 Categories	11 (10.4%)	2 (2.2%)	13 (6.5%)
		Worsened by 2 Categories	18 (17.0%)	2 (2.2%)	20 (10.1%)
		Worsened by 1 Category	21 (19.8%)	8 (8.6%)	29 (14.6%)
		No Change	42 (39.6%)	58 (62.4%)	100 (50.3%)
		Improved by ≥1 Categories	14 (13.2%)	23 (24.7%)	37 (18.6%)
	C5D1		N=92	N=76	N=168
		Worsened by ≥3 Categories	9 (9.8%)	1 (1.3%)	10 (6.0%)
		Worsened by 2 Categories	15 (16.3%)	3 (3.9%)	18 (10.7%)
		Worsened by 1 Category	11 (12.0%)	10 (13.2%)	21 (12.5%)
		No Change	45 (48.9%)	48 (63.2%)	93 (55.4%)
		Improved by ≥1 Categories	12 (13.0%)	14 (18.4%)	26 (15.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C6D1		N=90	N=70	N=160
		Worsened by ≥3 Categories	11 (12.2%)	0 (0.0%)	11 (6.9%)
		Worsened by 2 Categories	11 (12.2%)	3 (4.3%)	14 (8.8%)
		Worsened by 1 Category	12 (13.3%)	9 (12.9%)	21 (13.1%)
		No Change	42 (46.7%)	45 (64.3%)	87 (54.4%)
		Improved by ≥1 Categories	14 (15.6%)	13 (18.6%)	27 (16.9%)
	C7D1		N=74	N=52	N=126
		Worsened by ≥3 Categories	2 (2.7%)	2 (3.8%)	4 (3.2%)
		Worsened by 2 Categories	11 (14.9%)	0 (0.0%)	11 (8.7%)
		Worsened by 1 Category	18 (24.3%)	5 (9.6%)	23 (18.3%)
		No Change	28 (37.8%)	31 (59.6%)	59 (46.8%)
		Improved by ≥1 Categories	15 (20.3%)	14 (26.9%)	29 (23.0%)
	C8D1		N=70	N=49	N=119
		Worsened by ≥3 Categories	2 (2.9%)	0 (0.0%)	2 (1.7%)
		Worsened by 2 Categories	8 (11.4%)	2 (4.1%)	10 (8.4%)
		Worsened by 1 Category	14 (20.0%)	6 (12.2%)	20 (16.8%)
		No Change	35 (50.0%)	26 (53.1%)	61 (51.3%)
		Improved by ≥1 Categories	11 (15.7%)	15 (30.6%)	26 (21.8%)
	C9D1		N=56	N=41	N=97
		Worsened by ≥3 Categories	5 (8.9%)	3 (7.3%)	8 (8.2%)
		Worsened by 2 Categories	2 (3.6%)	1 (2.4%)	3 (3.1%)
		Worsened by 1 Category	8 (14.3%)	1 (2.4%)	9 (9.3%)
		No Change	32 (57.1%)	24 (58.5%)	56 (57.7%)
		Improved by ≥1 Categories	9 (16.1%)	12 (29.3%)	21 (21.6%)
	C10D1		N=49	N=30	N=79
		Worsened by ≥3 Categories	3 (6.1%)	2 (6.7%)	5 (6.3%)
		Worsened by 2 Categories	5 (10.2%)	2 (6.7%)	7 (8.9%)
		Worsened by 1 Category	8 (16.3%)	1 (3.3%)	9 (11.4%)
		No Change	23 (46.9%)	18 (60.0%)	41 (51.9%)
		Improved by ≥1 Categories	10 (20.4%)	7 (23.3%)	17 (21.5%)
	C11D1		N=42	N=23	N=65
		Worsened by ≥3 Categories	2 (4.8%)	0 (0.0%)	2 (3.1%)
		Worsened by 2 Categories	2 (4.8%)	2 (8.7%)	4 (6.2%)
		Worsened by 1 Category	6 (14.3%)	1 (4.3%)	7 (10.8%)
		No Change	23 (54.8%)	13 (56.5%)	36 (55.4%)
		Improved by ≥1 Categories	9 (21.4%)	7 (30.4%)	16 (24.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C12D1		N=38	N=19	N=57
		Worsened by ≥3 Categories	3 (7.9%)	0 (0.0%)	3 (5.3%)
		Worsened by 2 Categories	1 (2.6%)	1 (5.3%)	2 (3.5%)
		Worsened by 1 Category	8 (21.1%)	2 (10.5%)	10 (17.5%)
		No Change	18 (47.4%)	9 (47.4%)	27 (47.4%)
		Improved by ≥1 Categories	8 (21.1%)	7 (36.8%)	15 (26.3%)
	C13D1		N=31	N=13	N=44
		Worsened by ≥3 Categories	1 (3.2%)	0 (0.0%)	1 (2.3%)
		Worsened by 2 Categories	5 (16.1%)	0 (0.0%)	5 (11.4%)
		Worsened by 1 Category	6 (19.4%)	1 (7.7%)	7 (15.9%)
		No Change	12 (38.7%)	5 (38.5%)	17 (38.6%)
		Improved by ≥1 Categories	7 (22.6%)	7 (53.8%)	14 (31.8%)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	8 (25.8%)	0 (0.0%)	8 (18.6%)
		Worsened by 1 Category	4 (12.9%)	2 (16.7%)	6 (14.0%)
		No Change	15 (48.4%)	5 (41.7%)	20 (46.5%)
		Improved by ≥1 Categories	4 (12.9%)	5 (41.7%)	9 (20.9%)
	C15D1		N=26	N=12	N=38
		Worsened by ≥3 Categories	2 (7.7%)	0 (0.0%)	2 (5.3%)
		Worsened by 2 Categories	3 (11.5%)	0 (0.0%)	3 (7.9%)
		Worsened by 1 Category	6 (23.1%)	2 (16.7%)	8 (21.1%)
		No Change	10 (38.5%)	5 (41.7%)	15 (39.5%)
		Improved by ≥1 Categories	5 (19.2%)	5 (41.7%)	10 (26.3%)
	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	4 (15.4%)	0 (0.0%)	4 (11.1%)
		Worsened by 2 Categories	3 (11.5%)	0 (0.0%)	3 (8.3%)
		Worsened by 1 Category	3 (11.5%)	1 (10.0%)	4 (11.1%)
		No Change	10 (38.5%)	6 (60.0%)	16 (44.4%)
		Improved by ≥1 Categories	6 (23.1%)	3 (30.0%)	9 (25.0%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	2 (8.3%)	0 (0.0%)	2 (6.5%)
		Worsened by 2 Categories	5 (20.8%)	0 (0.0%)	5 (16.1%)
		Worsened by 1 Category	2 (8.3%)	1 (14.3%)	3 (9.7%)
		No Change	9 (37.5%)	3 (42.9%)	12 (38.7%)
		Improved by ≥1 Categories	6 (25.0%)	3 (42.9%)	9 (29.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	1 (5.0%)	0 (0.0%)	1 (3.7%)
		Worsened by 2 Categories	2 (10.0%)	1 (14.3%)	3 (11.1%)
		Worsened by 1 Category	3 (15.0%)	1 (14.3%)	4 (14.8%)
		No Change	9 (45.0%)	3 (42.9%)	12 (44.4%)
		Improved by ≥1 Categories	5 (25.0%)	2 (28.6%)	7 (25.9%)
	C19D1		N=19	N=6	N=25
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (5.3%)	0 (0.0%)	1 (4.0%)
		Worsened by 1 Category	4 (21.1%)	1 (16.7%)	5 (20.0%)
		No Change	9 (47.4%)	3 (50.0%)	12 (48.0%)
		Improved by ≥1 Categories	5 (26.3%)	2 (33.3%)	7 (28.0%)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Worsened by 2 Categories	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Worsened by 1 Category	2 (10.5%)	0 (0.0%)	2 (8.7%)
		No Change	11 (57.9%)	3 (75.0%)	14 (60.9%)
		Improved by ≥1 Categories	4 (21.1%)	1 (25.0%)	5 (21.7%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (17.6%)	0 (0.0%)	3 (14.3%)
		Worsened by 1 Category	1 (5.9%)	0 (0.0%)	1 (4.8%)
		No Change	8 (47.1%)	3 (75.0%)	11 (52.4%)
		Improved by ≥1 Categories	5 (29.4%)	1 (25.0%)	6 (28.6%)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (20.0%)	0 (0.0%)	3 (16.7%)
		Worsened by 1 Category	2 (13.3%)	1 (33.3%)	3 (16.7%)
		No Change	7 (46.7%)	1 (33.3%)	8 (44.4%)
		Improved by ≥1 Categories	3 (20.0%)	1 (33.3%)	4 (22.2%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (11.1%)	0 (0.0%)	1 (8.3%)
		Worsened by 1 Category	2 (22.2%)	1 (33.3%)	3 (25.0%)
		No Change	2 (22.2%)	1 (33.3%)	3 (25.0%)
		Improved by ≥1 Categories	4 (44.4%)	1 (33.3%)	5 (41.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (11.1%)	0 (0.0%)	1 (9.1%)
		Worsened by 1 Category	1 (11.1%)	1 (50.0%)	2 (18.2%)
		No Change	4 (44.4%)	0 (0.0%)	4 (36.4%)
		Improved by ≥1 Categories	3 (33.3%)	1 (50.0%)	4 (36.4%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	1 (12.5%)	0 (NE)	1 (12.5%)
		Worsened by 1 Category	1 (12.5%)	0 (NE)	1 (12.5%)
		No Change	3 (37.5%)	0 (NE)	3 (37.5%)
		Improved by ≥1 Categories	3 (37.5%)	0 (NE)	3 (37.5%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (0.0%)	1 (12.5%)
		No Change	3 (42.9%)	0 (0.0%)	3 (37.5%)
		Improved by ≥1 Categories	2 (28.6%)	1 (100.0%)	3 (37.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (28.6%)	0 (0.0%)	2 (25.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (42.9%)	0 (0.0%)	3 (37.5%)
		Improved by ≥1 Categories	2 (28.6%)	1 (100.0%)	3 (37.5%)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (16.7%)	0 (0.0%)	1 (14.3%)
		Worsened by 1 Category	1 (16.7%)	0 (0.0%)	1 (14.3%)
		No Change	3 (50.0%)	0 (0.0%)	3 (42.9%)
		Improved by ≥1 Categories	1 (16.7%)	1 (100.0%)	2 (28.6%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (25.0%)	0 (0.0%)	1 (20.0%)
		No Change	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Improved by ≥1 Categories	1 (25.0%)	1 (100.0%)	2 (40.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (75.0%)	0 (0.0%)	3 (60.0%)
		No Change	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (20.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (0.0%)	1 (33.3%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (33.3%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (0.0%)	1 (33.3%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (33.3%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (0.0%)	1 (25.0%)
		No Change	2 (66.7%)	0 (0.0%)	2 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	1 (100.0%)	1 (25.0%)
	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	2 (66.7%)	0 (NE)	2 (66.7%)
		No Change	1 (33.3%)	0 (NE)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	0 (NE)	1 (33.3%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	1 (33.3%)	0 (NE)	1 (33.3%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (66.7%)	0 (NE)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=124	N=122	N=246
		Worsened by ≥3 Categories	10 (8.1%)	1 (0.8%)	11 (4.5%)
		Worsened by 2 Categories	11 (8.9%)	9 (7.4%)	20 (8.1%)
		Worsened by 1 Category	16 (12.9%)	17 (13.9%)	33 (13.4%)
		No Change	74 (59.7%)	71 (58.2%)	145 (58.9%)
		Improved by ≥1 Categories	13 (10.5%)	24 (19.7%)	37 (15.0%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 2 Categories	2 (14.3%)	0 (0.0%)	2 (8.7%)
		Worsened by 1 Category	3 (21.4%)	3 (33.3%)	6 (26.1%)
		No Change	9 (64.3%)	4 (44.4%)	13 (56.5%)
		Improved by ≥1 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
Abdominal Pain Frequency	C2D1		N=149	N=144	N=293
		Worsened by ≥3 Categories	8 (5.4%)	1 (0.7%)	9 (3.1%)
		Worsened by 2 Categories	11 (7.4%)	14 (9.7%)	25 (8.5%)
		Worsened by 1 Category	28 (18.8%)	24 (16.7%)	52 (17.7%)
		No Change	75 (50.3%)	78 (54.2%)	153 (52.2%)
		Improved by ≥1 Categories	27 (18.1%)	27 (18.8%)	54 (18.4%)
	C3D1		N=116	N=102	N=218
		Worsened by ≥3 Categories	0 (0.0%)	2 (2.0%)	2 (0.9%)
		Worsened by 2 Categories	11 (9.5%)	12 (11.8%)	23 (10.6%)
		Worsened by 1 Category	15 (12.9%)	12 (11.8%)	27 (12.4%)
		No Change	65 (56.0%)	53 (52.0%)	118 (54.1%)
		Improved by ≥1 Categories	25 (21.6%)	23 (22.5%)	48 (22.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=106	N=93	N=199
		Worsened by ≥3 Categories	2 (1.9%)	0 (0.0%)	2 (1.0%)
		Worsened by 2 Categories	8 (7.5%)	7 (7.5%)	15 (7.5%)
		Worsened by 1 Category	15 (14.2%)	12 (12.9%)	27 (13.6%)
		No Change	53 (50.0%)	51 (54.8%)	104 (52.3%)
		Improved by ≥1 Categories	28 (26.4%)	23 (24.7%)	51 (25.6%)
	C5D1		N=92	N=79	N=171
		Worsened by ≥3 Categories	1 (1.1%)	1 (1.3%)	2 (1.2%)
		Worsened by 2 Categories	9 (9.8%)	5 (6.3%)	14 (8.2%)
		Worsened by 1 Category	15 (16.3%)	13 (16.5%)	28 (16.4%)
		No Change	40 (43.5%)	43 (54.4%)	83 (48.5%)
		Improved by ≥1 Categories	27 (29.3%)	17 (21.5%)	44 (25.7%)
	C6D1		N=90	N=70	N=160
		Worsened by ≥3 Categories	1 (1.1%)	1 (1.4%)	2 (1.3%)
		Worsened by 2 Categories	3 (3.3%)	1 (1.4%)	4 (2.5%)
		Worsened by 1 Category	16 (17.8%)	10 (14.3%)	26 (16.3%)
		No Change	45 (50.0%)	40 (57.1%)	85 (53.1%)
		Improved by ≥1 Categories	25 (27.8%)	18 (25.7%)	43 (26.9%)
	C7D1		N=75	N=54	N=129
		Worsened by ≥3 Categories	0 (0.0%)	2 (3.7%)	2 (1.6%)
		Worsened by 2 Categories	4 (5.3%)	0 (0.0%)	4 (3.1%)
		Worsened by 1 Category	13 (17.3%)	6 (11.1%)	19 (14.7%)
		No Change	42 (56.0%)	31 (57.4%)	73 (56.6%)
		Improved by ≥1 Categories	16 (21.3%)	15 (27.8%)	31 (24.0%)
	C8D1		N=69	N=50	N=119
		Worsened by ≥3 Categories	1 (1.4%)	0 (0.0%)	1 (0.8%)
		Worsened by 2 Categories	4 (5.8%)	1 (2.0%)	5 (4.2%)
		Worsened by 1 Category	14 (20.3%)	3 (6.0%)	17 (14.3%)
		No Change	39 (56.5%)	31 (62.0%)	70 (58.8%)
		Improved by ≥1 Categories	11 (15.9%)	15 (30.0%)	26 (21.8%)
	C9D1		N=57	N=41	N=98
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (5.3%)	3 (7.3%)	6 (6.1%)
		Worsened by 1 Category	10 (17.5%)	2 (4.9%)	12 (12.2%)
		No Change	37 (64.9%)	21 (51.2%)	58 (59.2%)
		Improved by ≥1 Categories	7 (12.3%)	15 (36.6%)	22 (22.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=49	N=30	N=79
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	5 (10.2%)	3 (10.0%)	8 (10.1%)
		Worsened by 1 Category	10 (20.4%)	2 (6.7%)	12 (15.2%)
		No Change	25 (51.0%)	16 (53.3%)	41 (51.9%)
		Improved by ≥1 Categories	9 (18.4%)	9 (30.0%)	18 (22.8%)
	C11D1		N=42	N=23	N=65
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (7.1%)	1 (4.3%)	4 (6.2%)
		Worsened by 1 Category	7 (16.7%)	4 (17.4%)	11 (16.9%)
		No Change	24 (57.1%)	11 (47.8%)	35 (53.8%)
		Improved by ≥1 Categories	8 (19.0%)	7 (30.4%)	15 (23.1%)
	C12D1		N=39	N=19	N=58
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (5.1%)	1 (5.3%)	3 (5.2%)
		Worsened by 1 Category	8 (20.5%)	2 (10.5%)	10 (17.2%)
		No Change	22 (56.4%)	11 (57.9%)	33 (56.9%)
		Improved by ≥1 Categories	7 (17.9%)	5 (26.3%)	12 (20.7%)
	C13D1		N=31	N=14	N=45
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (9.7%)	1 (7.1%)	4 (8.9%)
		Worsened by 1 Category	4 (12.9%)	1 (7.1%)	5 (11.1%)
		No Change	20 (64.5%)	9 (64.3%)	29 (64.4%)
		Improved by ≥1 Categories	4 (12.9%)	3 (21.4%)	7 (15.6%)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (12.9%)	2 (16.7%)	6 (14.0%)
		Worsened by 1 Category	4 (12.9%)	2 (16.7%)	6 (14.0%)
		No Change	19 (61.3%)	7 (58.3%)	26 (60.5%)
		Improved by ≥1 Categories	4 (12.9%)	1 (8.3%)	5 (11.6%)
	C15D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (7.7%)	1 (2.6%)
		Worsened by 1 Category	6 (23.1%)	3 (23.1%)	9 (23.1%)
		No Change	14 (53.8%)	6 (46.2%)	20 (51.3%)
		Improved by ≥1 Categories	6 (23.1%)	3 (23.1%)	9 (23.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (7.7%)	0 (0.0%)	2 (5.6%)
		Worsened by 1 Category	5 (19.2%)	2 (20.0%)	7 (19.4%)
		No Change	16 (61.5%)	8 (80.0%)	24 (66.7%)
		Improved by ≥1 Categories	3 (11.5%)	0 (0.0%)	3 (8.3%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	1 (4.2%)	0 (0.0%)	1 (3.2%)
		Worsened by 2 Categories	2 (8.3%)	0 (0.0%)	2 (6.5%)
		Worsened by 1 Category	2 (8.3%)	1 (14.3%)	3 (9.7%)
		No Change	16 (66.7%)	5 (71.4%)	21 (67.7%)
		Improved by ≥1 Categories	3 (12.5%)	1 (14.3%)	4 (12.9%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (15.0%)	1 (14.3%)	4 (14.8%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	14 (70.0%)	6 (85.7%)	20 (74.1%)
		Improved by ≥1 Categories	3 (15.0%)	0 (0.0%)	3 (11.1%)
	C19D1		N=19	N=6	N=25
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (15.8%)	0 (0.0%)	3 (12.0%)
		Worsened by 1 Category	2 (10.5%)	1 (16.7%)	3 (12.0%)
		No Change	10 (52.6%)	5 (83.3%)	15 (60.0%)
		Improved by ≥1 Categories	4 (21.1%)	0 (0.0%)	4 (16.0%)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.3%)	0 (0.0%)	1 (4.3%)
		No Change	14 (73.7%)	2 (50.0%)	16 (69.6%)
		Improved by ≥1 Categories	3 (15.8%)	2 (50.0%)	5 (21.7%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (11.8%)	0 (0.0%)	2 (9.5%)
		No Change	11 (64.7%)	3 (75.0%)	14 (66.7%)
		Improved by ≥1 Categories	4 (23.5%)	1 (25.0%)	5 (23.8%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (13.3%)	0 (0.0%)	2 (11.1%)
		Worsened by 1 Category	2 (13.3%)	0 (0.0%)	2 (11.1%)
		No Change	9 (60.0%)	3 (100.0%)	12 (66.7%)
		Improved by ≥1 Categories	2 (13.3%)	0 (0.0%)	2 (11.1%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (22.2%)	0 (0.0%)	2 (16.7%)
		No Change	6 (66.7%)	3 (100.0%)	9 (75.0%)
		Improved by ≥1 Categories	1 (11.1%)	0 (0.0%)	1 (8.3%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (22.2%)	1 (50.0%)	3 (27.3%)
		No Change	6 (66.7%)	1 (50.0%)	7 (63.6%)
		Improved by ≥1 Categories	1 (11.1%)	0 (0.0%)	1 (9.1%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	1 (12.5%)	0 (NE)	1 (12.5%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	6 (75.0%)	0 (NE)	6 (75.0%)
		Improved by ≥1 Categories	1 (12.5%)	0 (NE)	1 (12.5%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	3 (42.9%)	1 (100.0%)	4 (50.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	4 (57.1%)	1 (100.0%)	5 (62.5%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (16.7%)	0 (0.0%)	1 (14.3%)
		No Change	5 (83.3%)	1 (100.0%)	6 (85.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (20.0%)
		No Change	2 (50.0%)	0 (0.0%)	2 (40.0%)
		Improved by ≥1 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (50.0%)	0 (0.0%)	2 (40.0%)
		No Change	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=121	N=125	N=246
		Worsened by ≥3 Categories	3 (2.5%)	4 (3.2%)	7 (2.8%)
		Worsened by 2 Categories	11 (9.1%)	14 (11.2%)	25 (10.2%)
		Worsened by 1 Category	16 (13.2%)	12 (9.6%)	28 (11.4%)
		No Change	63 (52.1%)	67 (53.6%)	130 (52.8%)
		Improved by ≥1 Categories	28 (23.1%)	28 (22.4%)	56 (22.8%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (7.1%)	1 (11.1%)	2 (8.7%)
		Worsened by 1 Category	3 (21.4%)	2 (22.2%)	5 (21.7%)
		No Change	8 (57.1%)	4 (44.4%)	12 (52.2%)
		Improved by ≥1 Categories	2 (14.3%)	2 (22.2%)	4 (17.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Abdominal Pain Severity	C2D1		N=143	N=139	N=282
		Worsened by ≥3 Categories	2 (1.4%)	1 (0.7%)	3 (1.1%)
		Worsened by 2 Categories	11 (7.7%)	7 (5.0%)	18 (6.4%)
		Worsened by 1 Category	34 (23.8%)	26 (18.7%)	60 (21.3%)
		No Change	80 (55.9%)	76 (54.7%)	156 (55.3%)
		Improved by ≥1 Categories	16 (11.2%)	29 (20.9%)	45 (16.0%)
	C3D1		N=113	N=98	N=211
		Worsened by ≥3 Categories	0 (0.0%)	2 (2.0%)	2 (0.9%)
		Worsened by 2 Categories	5 (4.4%)	8 (8.2%)	13 (6.2%)
		Worsened by 1 Category	22 (19.5%)	15 (15.3%)	37 (17.5%)
		No Change	63 (55.8%)	49 (50.0%)	112 (53.1%)
		Improved by ≥1 Categories	23 (20.4%)	24 (24.5%)	47 (22.3%)
	C4D1		N=105	N=91	N=196
		Worsened by ≥3 Categories	1 (1.0%)	2 (2.2%)	3 (1.5%)
		Worsened by 2 Categories	8 (7.6%)	4 (4.4%)	12 (6.1%)
		Worsened by 1 Category	16 (15.2%)	17 (18.7%)	33 (16.8%)
		No Change	53 (50.5%)	44 (48.4%)	97 (49.5%)
		Improved by ≥1 Categories	27 (25.7%)	24 (26.4%)	51 (26.0%)
	C5D1		N=86	N=75	N=161
		Worsened by ≥3 Categories	1 (1.2%)	1 (1.3%)	2 (1.2%)
		Worsened by 2 Categories	4 (4.7%)	3 (4.0%)	7 (4.3%)
		Worsened by 1 Category	17 (19.8%)	13 (17.3%)	30 (18.6%)
		No Change	48 (55.8%)	42 (56.0%)	90 (55.9%)
		Improved by ≥1 Categories	16 (18.6%)	16 (21.3%)	32 (19.9%)
	C6D1		N=85	N=68	N=153
		Worsened by ≥3 Categories	2 (2.4%)	0 (0.0%)	2 (1.3%)
		Worsened by 2 Categories	3 (3.5%)	2 (2.9%)	5 (3.3%)
		Worsened by 1 Category	12 (14.1%)	9 (13.2%)	21 (13.7%)
		No Change	46 (54.1%)	37 (54.4%)	83 (54.2%)
		Improved by ≥1 Categories	22 (25.9%)	20 (29.4%)	42 (27.5%)
	C7D1		N=71	N=49	N=120
		Worsened by ≥3 Categories	0 (0.0%)	1 (2.0%)	1 (0.8%)
		Worsened by 2 Categories	2 (2.8%)	2 (4.1%)	4 (3.3%)
		Worsened by 1 Category	13 (18.3%)	5 (10.2%)	18 (15.0%)
		No Change	41 (57.7%)	30 (61.2%)	71 (59.2%)
		Improved by ≥1 Categories	15 (21.1%)	11 (22.4%)	26 (21.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C8D1		N=66	N=48	N=114
		Worsened by ≥3 Categories	2 (3.0%)	0 (0.0%)	2 (1.8%)
		Worsened by 2 Categories	1 (1.5%)	1 (2.1%)	2 (1.8%)
		Worsened by 1 Category	12 (18.2%)	3 (6.3%)	15 (13.2%)
		No Change	41 (62.1%)	32 (66.7%)	73 (64.0%)
		Improved by ≥1 Categories	10 (15.2%)	12 (25.0%)	22 (19.3%)
	C9D1		N=53	N=39	N=92
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	3 (7.7%)	3 (3.3%)
		Worsened by 1 Category	11 (20.8%)	3 (7.7%)	14 (15.2%)
		No Change	36 (67.9%)	23 (59.0%)	59 (64.1%)
		Improved by ≥1 Categories	6 (11.3%)	10 (25.6%)	16 (17.4%)
	C10D1		N=46	N=28	N=74
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.2%)	1 (3.6%)	2 (2.7%)
		Worsened by 1 Category	10 (21.7%)	6 (21.4%)	16 (21.6%)
		No Change	27 (58.7%)	15 (53.6%)	42 (56.8%)
		Improved by ≥1 Categories	8 (17.4%)	6 (21.4%)	14 (18.9%)
	C11D1		N=41	N=22	N=63
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (4.9%)	2 (9.1%)	4 (6.3%)
		Worsened by 1 Category	5 (12.2%)	2 (9.1%)	7 (11.1%)
		No Change	27 (65.9%)	12 (54.5%)	39 (61.9%)
		Improved by ≥1 Categories	7 (17.1%)	6 (27.3%)	13 (20.6%)
	C12D1		N=37	N=18	N=55
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (5.4%)	1 (5.6%)	3 (5.5%)
		Worsened by 1 Category	6 (16.2%)	1 (5.6%)	7 (12.7%)
		No Change	22 (59.5%)	12 (66.7%)	34 (61.8%)
		Improved by ≥1 Categories	7 (18.9%)	4 (22.2%)	11 (20.0%)
	C13D1		N=27	N=13	N=40
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (7.4%)	1 (7.7%)	3 (7.5%)
		Worsened by 1 Category	7 (25.9%)	0 (0.0%)	7 (17.5%)
		No Change	15 (55.6%)	8 (61.5%)	23 (57.5%)
		Improved by ≥1 Categories	3 (11.1%)	4 (30.8%)	7 (17.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C14D1		N=30	N=12	N=42
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (10.0%)	1 (8.3%)	4 (9.5%)
		Worsened by 1 Category	6 (20.0%)	3 (25.0%)	9 (21.4%)
		No Change	17 (56.7%)	6 (50.0%)	23 (54.8%)
		Improved by ≥1 Categories	4 (13.3%)	2 (16.7%)	6 (14.3%)
	C15D1		N=25	N=12	N=37
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.0%)	1 (8.3%)	2 (5.4%)
		Worsened by 1 Category	4 (16.0%)	1 (8.3%)	5 (13.5%)
		No Change	15 (60.0%)	9 (75.0%)	24 (64.9%)
		Improved by ≥1 Categories	5 (20.0%)	1 (8.3%)	6 (16.2%)
	C16D1		N=24	N=10	N=34
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.2%)	1 (10.0%)	2 (5.9%)
		Worsened by 1 Category	4 (16.7%)	1 (10.0%)	5 (14.7%)
		No Change	16 (66.7%)	7 (70.0%)	23 (67.6%)
		Improved by ≥1 Categories	3 (12.5%)	1 (10.0%)	4 (11.8%)
	C17D1		N=23	N=7	N=30
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (8.7%)	1 (14.3%)	3 (10.0%)
		Worsened by 1 Category	2 (8.7%)	0 (0.0%)	2 (6.7%)
		No Change	16 (69.6%)	4 (57.1%)	20 (66.7%)
		Improved by ≥1 Categories	3 (13.0%)	2 (28.6%)	5 (16.7%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (10.0%)	1 (14.3%)	3 (11.1%)
		Worsened by 1 Category	2 (10.0%)	0 (0.0%)	2 (7.4%)
		No Change	14 (70.0%)	4 (57.1%)	18 (66.7%)
		Improved by ≥1 Categories	2 (10.0%)	2 (28.6%)	4 (14.8%)
	C19D1		N=19	N=5	N=24
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (5.3%)	0 (0.0%)	1 (4.2%)
		Worsened by 1 Category	4 (21.1%)	1 (20.0%)	5 (20.8%)
		No Change	11 (57.9%)	2 (40.0%)	13 (54.2%)
		Improved by ≥1 Categories	3 (15.8%)	2 (40.0%)	5 (20.8%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C20D1		N=18	N=4	N=22
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (11.1%)	0 (0.0%)	2 (9.1%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	12 (66.7%)	2 (50.0%)	14 (63.6%)
		Improved by ≥1 Categories	4 (22.2%)	2 (50.0%)	6 (27.3%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (5.9%)	0 (0.0%)	1 (4.8%)
		No Change	12 (70.6%)	2 (50.0%)	14 (66.7%)
		Improved by ≥1 Categories	4 (23.5%)	2 (50.0%)	6 (28.6%)
	C22D1		N=14	N=3	N=17
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (7.1%)	0 (0.0%)	1 (5.9%)
		Worsened by 1 Category	4 (28.6%)	0 (0.0%)	4 (23.5%)
		No Change	8 (57.1%)	2 (66.7%)	10 (58.8%)
		Improved by ≥1 Categories	1 (7.1%)	1 (33.3%)	2 (11.8%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (22.2%)	0 (0.0%)	2 (16.7%)
		No Change	6 (66.7%)	2 (66.7%)	8 (66.7%)
		Improved by ≥1 Categories	1 (11.1%)	1 (33.3%)	2 (16.7%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (11.1%)	0 (0.0%)	1 (9.1%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (9.1%)
		No Change	6 (66.7%)	1 (50.0%)	7 (63.6%)
		Improved by ≥1 Categories	1 (11.1%)	1 (50.0%)	2 (18.2%)
	C25D1		N=7	N=0	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	2 (28.6%)	0 (NE)	2 (28.6%)
		No Change	4 (57.1%)	0 (NE)	4 (57.1%)
		Improved by ≥1 Categories	1 (14.3%)	0 (NE)	1 (14.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	3 (42.9%)	1 (100.0%)	4 (50.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (42.9%)	0 (0.0%)	3 (37.5%)
		No Change	3 (42.9%)	1 (100.0%)	4 (50.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (16.7%)	0 (0.0%)	1 (14.3%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (83.3%)	1 (100.0%)	6 (85.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (25.0%)	1 (100.0%)	2 (40.0%)
		No Change	2 (50.0%)	0 (0.0%)	2 (40.0%)
		Improved by ≥1 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (50.0%)	0 (0.0%)	2 (40.0%)
		No Change	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	EOT		N=114	N=118	N=232
		Worsened by ≥3 Categories	2 (1.8%)	4 (3.4%)	6 (2.6%)
		Worsened by 2 Categories	10 (8.8%)	8 (6.8%)	18 (7.8%)
		Worsened by 1 Category	16 (14.0%)	17 (14.4%)	33 (14.2%)
		No Change	67 (58.8%)	62 (52.5%)	129 (55.6%)
		Improved by ≥1 Categories	19 (16.7%)	27 (22.9%)	46 (19.8%)
	Long Term		N=14	N=8	N=22
	Follow-up	Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (14.3%)	1 (12.5%)	3 (13.6%)
		Worsened by 1 Category	2 (14.3%)	1 (12.5%)	3 (13.6%)
		No Change	8 (57.1%)	3 (37.5%)	11 (50.0%)
		Improved by ≥1 Categories	2 (14.3%)	3 (37.5%)	5 (22.7%)
Abdominal Pain Interference	C2D1		N=141	N=134	N=275
		Worsened by ≥3 Categories	3 (2.1%)	0 (0.0%)	3 (1.1%)
		Worsened by 2 Categories	3 (2.1%)	8 (6.0%)	11 (4.0%)
		Worsened by 1 Category	26 (18.4%)	16 (11.9%)	42 (15.3%)
		No Change	100 (70.9%)	93 (69.4%)	193 (70.2%)
		Improved by ≥1 Categories	9 (6.4%)	17 (12.7%)	26 (9.5%)
	C3D1		N=113	N=98	N=211
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (0.9%)	3 (3.1%)	4 (1.9%)
		Worsened by 1 Category	17 (15.0%)	16 (16.3%)	33 (15.6%)
		No Change	78 (69.0%)	67 (68.4%)	145 (68.7%)
		Improved by ≥1 Categories	17 (15.0%)	12 (12.2%)	29 (13.7%)
	C4D1		N=102	N=89	N=191
		Worsened by ≥3 Categories	2 (2.0%)	0 (0.0%)	2 (1.0%)
		Worsened by 2 Categories	4 (3.9%)	4 (4.5%)	8 (4.2%)
		Worsened by 1 Category	9 (8.8%)	11 (12.4%)	20 (10.5%)
		No Change	67 (65.7%)	61 (68.5%)	128 (67.0%)
		Improved by ≥1 Categories	20 (19.6%)	13 (14.6%)	33 (17.3%)
	C5D1		N=86	N=74	N=160
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	6 (7.0%)	7 (9.5%)	13 (8.1%)
		Worsened by 1 Category	8 (9.3%)	7 (9.5%)	15 (9.4%)
		No Change	58 (67.4%)	50 (67.6%)	108 (67.5%)
		Improved by ≥1 Categories	14 (16.3%)	10 (13.5%)	24 (15.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C6D1		N=83	N=67	N=150
		Worsened by ≥3 Categories	1 (1.2%)	0 (0.0%)	1 (0.7%)
		Worsened by 2 Categories	5 (6.0%)	2 (3.0%)	7 (4.7%)
		Worsened by 1 Category	7 (8.4%)	8 (11.9%)	15 (10.0%)
		No Change	59 (71.1%)	48 (71.6%)	107 (71.3%)
		Improved by ≥1 Categories	11 (13.3%)	9 (13.4%)	20 (13.3%)
	C7D1		N=70	N=48	N=118
		Worsened by ≥3 Categories	0 (0.0%)	1 (2.1%)	1 (0.8%)
		Worsened by 2 Categories	2 (2.9%)	3 (6.3%)	5 (4.2%)
		Worsened by 1 Category	6 (8.6%)	3 (6.3%)	9 (7.6%)
		No Change	54 (77.1%)	38 (79.2%)	92 (78.0%)
		Improved by ≥1 Categories	8 (11.4%)	3 (6.3%)	11 (9.3%)
	C8D1		N=67	N=46	N=113
		Worsened by ≥3 Categories	2 (3.0%)	0 (0.0%)	2 (1.8%)
		Worsened by 2 Categories	0 (0.0%)	2 (4.3%)	2 (1.8%)
		Worsened by 1 Category	7 (10.4%)	1 (2.2%)	8 (7.1%)
		No Change	52 (77.6%)	37 (80.4%)	89 (78.8%)
		Improved by ≥1 Categories	6 (9.0%)	6 (13.0%)	12 (10.6%)
	C9D1		N=50	N=38	N=88
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.0%)	2 (5.3%)	3 (3.4%)
		Worsened by 1 Category	7 (14.0%)	4 (10.5%)	11 (12.5%)
		No Change	33 (66.0%)	28 (73.7%)	61 (69.3%)
		Improved by ≥1 Categories	9 (18.0%)	4 (10.5%)	13 (14.8%)
	C10D1		N=45	N=27	N=72
		Worsened by ≥3 Categories	1 (2.2%)	1 (3.7%)	2 (2.8%)
		Worsened by 2 Categories	1 (2.2%)	2 (7.4%)	3 (4.2%)
		Worsened by 1 Category	5 (11.1%)	2 (7.4%)	7 (9.7%)
		No Change	32 (71.1%)	18 (66.7%)	50 (69.4%)
		Improved by ≥1 Categories	6 (13.3%)	4 (14.8%)	10 (13.9%)
	C11D1		N=41	N=22	N=63
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (4.5%)	1 (1.6%)
		Worsened by 1 Category	4 (9.8%)	3 (13.6%)	7 (11.1%)
		No Change	33 (80.5%)	15 (68.2%)	48 (76.2%)
		Improved by ≥1 Categories	4 (9.8%)	3 (13.6%)	7 (11.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C12D1		N=36	N=18	N=54
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.8%)	0 (0.0%)	1 (1.9%)
		Worsened by 1 Category	3 (8.3%)	1 (5.6%)	4 (7.4%)
		No Change	29 (80.6%)	16 (88.9%)	45 (83.3%)
		Improved by ≥1 Categories	3 (8.3%)	1 (5.6%)	4 (7.4%)
	C13D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (3.8%)	0 (0.0%)	1 (2.6%)
		Worsened by 1 Category	6 (23.1%)	1 (7.7%)	7 (17.9%)
		No Change	16 (61.5%)	12 (92.3%)	28 (71.8%)
		Improved by ≥1 Categories	3 (11.5%)	0 (0.0%)	3 (7.7%)
	C14D1		N=28	N=12	N=40
		Worsened by ≥3 Categories	1 (3.6%)	0 (0.0%)	1 (2.5%)
		Worsened by 2 Categories	1 (3.6%)	0 (0.0%)	1 (2.5%)
		Worsened by 1 Category	4 (14.3%)	2 (16.7%)	6 (15.0%)
		No Change	19 (67.9%)	10 (83.3%)	29 (72.5%)
		Improved by ≥1 Categories	3 (10.7%)	0 (0.0%)	3 (7.5%)
	C15D1		N=23	N=11	N=34
		Worsened by ≥3 Categories	1 (4.3%)	0 (0.0%)	1 (2.9%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (13.0%)	3 (27.3%)	6 (17.6%)
		No Change	17 (73.9%)	8 (72.7%)	25 (73.5%)
		Improved by ≥1 Categories	2 (8.7%)	0 (0.0%)	2 (5.9%)
	C16D1		N=23	N=10	N=33
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.3%)	0 (0.0%)	1 (3.0%)
		Worsened by 1 Category	1 (4.3%)	4 (40.0%)	5 (15.2%)
		No Change	18 (78.3%)	6 (60.0%)	24 (72.7%)
		Improved by ≥1 Categories	3 (13.0%)	0 (0.0%)	3 (9.1%)
	C17D1		N=22	N=6	N=28
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (9.1%)	0 (0.0%)	2 (7.1%)
		Worsened by 1 Category	2 (9.1%)	1 (16.7%)	3 (10.7%)
		No Change	17 (77.3%)	5 (83.3%)	22 (78.6%)
		Improved by ≥1 Categories	1 (4.5%)	0 (0.0%)	1 (3.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C18D1		N=19	N=7	N=26
		Worsened by ≥3 Categories	1 (5.3%)	0 (0.0%)	1 (3.8%)
		Worsened by 2 Categories	0 (0.0%)	1 (14.3%)	1 (3.8%)
		Worsened by 1 Category	2 (10.5%)	2 (28.6%)	4 (15.4%)
		No Change	15 (78.9%)	4 (57.1%)	19 (73.1%)
		Improved by ≥1 Categories	1 (5.3%)	0 (0.0%)	1 (3.8%)
	C19D1		N=18	N=5	N=23
		Worsened by ≥3 Categories	1 (5.6%)	0 (0.0%)	1 (4.3%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (11.1%)	2 (40.0%)	4 (17.4%)
		No Change	14 (77.8%)	2 (40.0%)	16 (69.6%)
		Improved by ≥1 Categories	1 (5.6%)	1 (20.0%)	2 (8.7%)
	C20D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (5.9%)	0 (0.0%)	1 (4.8%)
		Worsened by 1 Category	1 (5.9%)	0 (0.0%)	1 (4.8%)
		No Change	13 (76.5%)	3 (75.0%)	16 (76.2%)
		Improved by ≥1 Categories	2 (11.8%)	1 (25.0%)	3 (14.3%)
	C21D1		N=16	N=4	N=20
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (6.3%)	0 (0.0%)	1 (5.0%)
		No Change	13 (81.3%)	4 (100.0%)	17 (85.0%)
		Improved by ≥1 Categories	2 (12.5%)	0 (0.0%)	2 (10.0%)
	C22D1		N=13	N=3	N=16
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (7.7%)	0 (0.0%)	1 (6.3%)
		Worsened by 1 Category	3 (23.1%)	1 (33.3%)	4 (25.0%)
		No Change	9 (69.2%)	2 (66.7%)	11 (68.8%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C23D1		N=8	N=3	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	8 (100.0%)	3 (100.0%)	11 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C24D1		N=8	N=2	N=10
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (50.0%)	1 (10.0%)
		No Change	8 (100.0%)	1 (50.0%)	9 (90.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C25D1		N=6	N=0	N=6
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	2 (33.3%)	0 (NE)	2 (33.3%)
		No Change	4 (66.7%)	0 (NE)	4 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C26D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (16.7%)	0 (0.0%)	1 (14.3%)
		Worsened by 1 Category	1 (16.7%)	0 (0.0%)	1 (14.3%)
		No Change	4 (66.7%)	1 (100.0%)	5 (71.4%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (16.7%)	0 (0.0%)	1 (14.3%)
		No Change	5 (83.3%)	1 (100.0%)	6 (85.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=5	N=1	N=6
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (20.0%)	0 (0.0%)	1 (16.7%)
		No Change	4 (80.0%)	1 (100.0%)	5 (83.3%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (33.3%)	1 (100.0%)	2 (50.0%)
		No Change	2 (66.7%)	0 (0.0%)	2 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (25.0%)	0 (0.0%)	1 (20.0%)
		No Change	3 (75.0%)	1 (100.0%)	4 (80.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C36D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=109	N=112	N=221
		Worsened by ≥3 Categories	2 (1.8%)	6 (5.4%)	8 (3.6%)
		Worsened by 2 Categories	10 (9.2%)	6 (5.4%)	16 (7.2%)
		Worsened by 1 Category	11 (10.1%)	19 (17.0%)	30 (13.6%)
		No Change	73 (67.0%)	64 (57.1%)	137 (62.0%)
		Improved by ≥1 Categories	13 (11.9%)	17 (15.2%)	30 (13.6%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	1 (7.1%)	1 (11.1%)	2 (8.7%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (14.3%)	2 (22.2%)	4 (17.4%)
		No Change	10 (71.4%)	3 (33.3%)	13 (56.5%)
		Improved by ≥1 Categories	1 (7.1%)	3 (33.3%)	4 (17.4%)
Shortness of Breath Severity	C2D1		N=148	N=143	N=291
		Worsened by ≥3 Categories	1 (0.7%)	0 (0.0%)	1 (0.3%)
		Worsened by 2 Categories	4 (2.7%)	5 (3.5%)	9 (3.1%)
		Worsened by 1 Category	26 (17.6%)	25 (17.5%)	51 (17.5%)
		No Change	92 (62.2%)	92 (64.3%)	184 (63.2%)
		Improved by ≥1 Categories	25 (16.9%)	21 (14.7%)	46 (15.8%)
	C3D1		N=116	N=102	N=218
		Worsened by ≥3 Categories	0 (0.0%)	2 (2.0%)	2 (0.9%)
		Worsened by 2 Categories	2 (1.7%)	2 (2.0%)	4 (1.8%)
		Worsened by 1 Category	19 (16.4%)	20 (19.6%)	39 (17.9%)
		No Change	76 (65.5%)	62 (60.8%)	138 (63.3%)
		Improved by ≥1 Categories	19 (16.4%)	16 (15.7%)	35 (16.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=104	N=93	N=197
		Worsened by ≥3 Categories	0 (0.0%)	1 (1.1%)	1 (0.5%)
		Worsened by 2 Categories	5 (4.8%)	4 (4.3%)	9 (4.6%)
		Worsened by 1 Category	19 (18.3%)	16 (17.2%)	35 (17.8%)
		No Change	60 (57.7%)	56 (60.2%)	116 (58.9%)
		Improved by ≥1 Categories	20 (19.2%)	16 (17.2%)	36 (18.3%)
	C5D1		N=92	N=79	N=171
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (2.2%)	2 (2.5%)	4 (2.3%)
		Worsened by 1 Category	20 (21.7%)	17 (21.5%)	37 (21.6%)
		No Change	52 (56.5%)	46 (58.2%)	98 (57.3%)
		Improved by ≥1 Categories	18 (19.6%)	14 (17.7%)	32 (18.7%)
	C6D1		N=88	N=70	N=158
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (1.1%)	3 (4.3%)	4 (2.5%)
		Worsened by 1 Category	13 (14.8%)	11 (15.7%)	24 (15.2%)
		No Change	57 (64.8%)	42 (60.0%)	99 (62.7%)
		Improved by ≥1 Categories	17 (19.3%)	14 (20.0%)	31 (19.6%)
	C7D1		N=75	N=54	N=129
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (1.9%)	1 (0.8%)
		Worsened by 1 Category	12 (16.0%)	8 (14.8%)	20 (15.5%)
		No Change	49 (65.3%)	32 (59.3%)	81 (62.8%)
		Improved by ≥1 Categories	14 (18.7%)	13 (24.1%)	27 (20.9%)
	C8D1		N=70	N=50	N=120
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	2 (4.0%)	2 (1.7%)
		Worsened by 1 Category	13 (18.6%)	8 (16.0%)	21 (17.5%)
		No Change	44 (62.9%)	31 (62.0%)	75 (62.5%)
		Improved by ≥1 Categories	13 (18.6%)	9 (18.0%)	22 (18.3%)
	C9D1		N=57	N=41	N=98
		Worsened by ≥3 Categories	0 (0.0%)	1 (2.4%)	1 (1.0%)
		Worsened by 2 Categories	1 (1.8%)	0 (0.0%)	1 (1.0%)
		Worsened by 1 Category	6 (10.5%)	6 (14.6%)	12 (12.2%)
		No Change	40 (70.2%)	26 (63.4%)	66 (67.3%)
		Improved by ≥1 Categories	10 (17.5%)	8 (19.5%)	18 (18.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=49	N=30	N=79
		Worsened by ≥3 Categories	1 (2.0%)	1 (3.3%)	2 (2.5%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	7 (14.3%)	6 (20.0%)	13 (16.5%)
		No Change	29 (59.2%)	18 (60.0%)	47 (59.5%)
		Improved by ≥1 Categories	12 (24.5%)	5 (16.7%)	17 (21.5%)
	C11D1		N=43	N=23	N=66
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	7 (16.3%)	7 (30.4%)	14 (21.2%)
		No Change	28 (65.1%)	13 (56.5%)	41 (62.1%)
		Improved by ≥1 Categories	8 (18.6%)	3 (13.0%)	11 (16.7%)
	C12D1		N=39	N=19	N=58
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	8 (20.5%)	6 (31.6%)	14 (24.1%)
		No Change	24 (61.5%)	11 (57.9%)	35 (60.3%)
		Improved by ≥1 Categories	7 (17.9%)	2 (10.5%)	9 (15.5%)
	C13D1		N=31	N=14	N=45
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	6 (19.4%)	4 (28.6%)	10 (22.2%)
		No Change	20 (64.5%)	8 (57.1%)	28 (62.2%)
		Improved by ≥1 Categories	5 (16.1%)	2 (14.3%)	7 (15.6%)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	4 (12.9%)	2 (16.7%)	6 (14.0%)
		No Change	23 (74.2%)	9 (75.0%)	32 (74.4%)
		Improved by ≥1 Categories	4 (12.9%)	1 (8.3%)	5 (11.6%)
	C15D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	0 (0.0%)	1 (7.7%)	1 (2.6%)
		Worsened by 2 Categories	0 (0.0%)	1 (7.7%)	1 (2.6%)
		Worsened by 1 Category	6 (23.1%)	4 (30.8%)	10 (25.6%)
		No Change	16 (61.5%)	5 (38.5%)	21 (53.8%)
		Improved by ≥1 Categories	4 (15.4%)	2 (15.4%)	6 (15.4%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
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	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	4 (15.4%)	3 (30.0%)	7 (19.4%)
		No Change	19 (73.1%)	6 (60.0%)	25 (69.4%)
		Improved by ≥1 Categories	3 (11.5%)	1 (10.0%)	4 (11.1%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (4.2%)	0 (0.0%)	1 (3.2%)
		Worsened by 1 Category	2 (8.3%)	1 (14.3%)	3 (9.7%)
		No Change	19 (79.2%)	5 (71.4%)	24 (77.4%)
		Improved by ≥1 Categories	2 (8.3%)	1 (14.3%)	3 (9.7%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (14.3%)	1 (3.7%)
		Worsened by 1 Category	3 (15.0%)	1 (14.3%)	4 (14.8%)
		No Change	13 (65.0%)	4 (57.1%)	17 (63.0%)
		Improved by ≥1 Categories	4 (20.0%)	1 (14.3%)	5 (18.5%)
	C19D1		N=19	N=6	N=25
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	4 (21.1%)	3 (50.0%)	7 (28.0%)
		No Change	11 (57.9%)	2 (33.3%)	13 (52.0%)
		Improved by ≥1 Categories	4 (21.1%)	1 (16.7%)	5 (20.0%)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Worsened by 1 Category	3 (15.8%)	1 (25.0%)	4 (17.4%)
		No Change	11 (57.9%)	2 (50.0%)	13 (56.5%)
		Improved by ≥1 Categories	4 (21.1%)	1 (25.0%)	5 (21.7%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (11.8%)	1 (25.0%)	3 (14.3%)
		No Change	13 (76.5%)	2 (50.0%)	15 (71.4%)
		Improved by ≥1 Categories	2 (11.8%)	1 (25.0%)	3 (14.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (20.0%)	1 (33.3%)	4 (22.2%)
		No Change	10 (66.7%)	1 (33.3%)	11 (61.1%)
		Improved by ≥1 Categories	2 (13.3%)	1 (33.3%)	3 (16.7%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (8.3%)
		No Change	5 (55.6%)	2 (66.7%)	7 (58.3%)
		Improved by ≥1 Categories	3 (33.3%)	1 (33.3%)	4 (33.3%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (9.1%)
		No Change	5 (55.6%)	1 (50.0%)	6 (54.5%)
		Improved by ≥1 Categories	3 (33.3%)	1 (50.0%)	4 (36.4%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (12.5%)	0 (NE)	1 (12.5%)
		No Change	3 (37.5%)	0 (NE)	3 (37.5%)
		Improved by ≥1 Categories	4 (50.0%)	0 (NE)	4 (50.0%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	3 (42.9%)	1 (100.0%)	4 (50.0%)
		Improved by ≥1 Categories	2 (28.6%)	0 (0.0%)	2 (25.0%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	4 (57.1%)	1 (100.0%)	5 (62.5%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (16.7%)	0 (0.0%)	1 (14.3%)
		No Change	4 (66.7%)	1 (100.0%)	5 (71.4%)
		Improved by ≥1 Categories	1 (16.7%)	0 (0.0%)	1 (14.3%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (75.0%)	1 (100.0%)	4 (80.0%)
		Improved by ≥1 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (20.0%)
		No Change	4 (100.0%)	0 (0.0%)	4 (80.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (33.3%)
		No Change	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (33.3%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	1 (50.0%)	0 (0.0%)	1 (33.3%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (25.0%)
		No Change	2 (66.7%)	0 (0.0%)	2 (50.0%)
		Improved by ≥1 Categories	1 (33.3%)	0 (0.0%)	1 (25.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=122	N=123	N=245
		Worsened by ≥3 Categories	2 (1.6%)	5 (4.1%)	7 (2.9%)
		Worsened by 2 Categories	2 (1.6%)	4 (3.3%)	6 (2.4%)
		Worsened by 1 Category	26 (21.3%)	24 (19.5%)	50 (20.4%)
		No Change	73 (59.8%)	70 (56.9%)	143 (58.4%)
		Improved by ≥1 Categories	19 (15.6%)	20 (16.3%)	39 (15.9%)
	Long Term Follow-up		N=14	N=8	N=22
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	4 (28.6%)	2 (25.0%)	6 (27.3%)
		No Change	7 (50.0%)	5 (62.5%)	12 (54.5%)
		Improved by ≥1 Categories	3 (21.4%)	1 (12.5%)	4 (18.2%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Shortness of Breath	C2D1		N=143	N=139	N=282
Interference		Worsened by ≥3 Categories	4 (2.8%)	3 (2.2%)	7 (2.5%)
		Worsened by 2 Categories	6 (4.2%)	2 (1.4%)	8 (2.8%)
		Worsened by 1 Category	18 (12.6%)	21 (15.1%)	39 (13.8%)
		No Change	97 (67.8%)	94 (67.6%)	191 (67.7%)
		Improved by ≥1 Categories	18 (12.6%)	19 (13.7%)	37 (13.1%)
	C3D1		N=112	N=97	N=209
		Worsened by ≥3 Categories	0 (0.0%)	1 (1.0%)	1 (0.5%)
		Worsened by 2 Categories	2 (1.8%)	4 (4.1%)	6 (2.9%)
		Worsened by 1 Category	20 (17.9%)	15 (15.5%)	35 (16.7%)
		No Change	72 (64.3%)	63 (64.9%)	135 (64.6%)
		Improved by ≥1 Categories	18 (16.1%)	14 (14.4%)	32 (15.3%)
	C4D1		N=100	N=89	N=189
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (4.0%)	6 (6.7%)	10 (5.3%)
		Worsened by 1 Category	19 (19.0%)	14 (15.7%)	33 (17.5%)
		No Change	61 (61.0%)	55 (61.8%)	116 (61.4%)
		Improved by ≥1 Categories	16 (16.0%)	14 (15.7%)	30 (15.9%)
	C5D1		N=86	N=73	N=159
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	4 (4.7%)	2 (2.7%)	6 (3.8%)
		Worsened by 1 Category	11 (12.8%)	10 (13.7%)	21 (13.2%)
		No Change	57 (66.3%)	50 (68.5%)	107 (67.3%)
		Improved by ≥1 Categories	14 (16.3%)	11 (15.1%)	25 (15.7%)
	C6D1		N=82	N=66	N=148
		Worsened by ≥3 Categories	0 (0.0%)	1 (1.5%)	1 (0.7%)
		Worsened by 2 Categories	0 (0.0%)	2 (3.0%)	2 (1.4%)
		Worsened by 1 Category	13 (15.9%)	9 (13.6%)	22 (14.9%)
		No Change	55 (67.1%)	41 (62.1%)	96 (64.9%)
		Improved by ≥1 Categories	14 (17.1%)	13 (19.7%)	27 (18.2%)
	C7D1		N=71	N=47	N=118
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (1.4%)	0 (0.0%)	1 (0.8%)
		Worsened by 1 Category	9 (12.7%)	5 (10.6%)	14 (11.9%)
		No Change	48 (67.6%)	35 (74.5%)	83 (70.3%)
		Improved by ≥1 Categories	13 (18.3%)	7 (14.9%)	20 (16.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C8D1		N=67	N=45	N=112
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	3 (4.5%)	2 (4.4%)	5 (4.5%)
		Worsened by 1 Category	7 (10.4%)	5 (11.1%)	12 (10.7%)
		No Change	46 (68.7%)	33 (73.3%)	79 (70.5%)
		Improved by ≥1 Categories	11 (16.4%)	5 (11.1%)	16 (14.3%)
	C9D1		N=52	N=38	N=90
		Worsened by ≥3 Categories	0 (0.0%)	1 (2.6%)	1 (1.1%)
		Worsened by 2 Categories	3 (5.8%)	0 (0.0%)	3 (3.3%)
		Worsened by 1 Category	3 (5.8%)	3 (7.9%)	6 (6.7%)
		No Change	38 (73.1%)	29 (76.3%)	67 (74.4%)
		Improved by ≥1 Categories	8 (15.4%)	5 (13.2%)	13 (14.4%)
	C10D1		N=44	N=28	N=72
		Worsened by ≥3 Categories	1 (2.3%)	0 (0.0%)	1 (1.4%)
		Worsened by 2 Categories	0 (0.0%)	2 (7.1%)	2 (2.8%)
		Worsened by 1 Category	5 (11.4%)	3 (10.7%)	8 (11.1%)
		No Change	29 (65.9%)	18 (64.3%)	47 (65.3%)
		Improved by ≥1 Categories	9 (20.5%)	5 (17.9%)	14 (19.4%)
	C11D1		N=40	N=22	N=62
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.5%)	0 (0.0%)	1 (1.6%)
		Worsened by 1 Category	5 (12.5%)	6 (27.3%)	11 (17.7%)
		No Change	26 (65.0%)	13 (59.1%)	39 (62.9%)
		Improved by ≥1 Categories	8 (20.0%)	3 (13.6%)	11 (17.7%)
	C12D1		N=37	N=18	N=55
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.7%)	0 (0.0%)	1 (1.8%)
		Worsened by 1 Category	6 (16.2%)	3 (16.7%)	9 (16.4%)
		No Change	25 (67.6%)	14 (77.8%)	39 (70.9%)
		Improved by ≥1 Categories	5 (13.5%)	1 (5.6%)	6 (10.9%)
	C13D1		N=29	N=13	N=42
		Worsened by ≥3 Categories	1 (3.4%)	0 (0.0%)	1 (2.4%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	5 (17.2%)	4 (30.8%)	9 (21.4%)
		No Change	17 (58.6%)	8 (61.5%)	25 (59.5%)
		Improved by ≥1 Categories	6 (20.7%)	1 (7.7%)	7 (16.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C14D1		N=30	N=12	N=42
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	6 (20.0%)	2 (16.7%)	8 (19.0%)
		No Change	19 (63.3%)	9 (75.0%)	28 (66.7%)
		Improved by ≥1 Categories	5 (16.7%)	1 (8.3%)	6 (14.3%)
	C15D1		N=25	N=12	N=37
		Worsened by ≥3 Categories	0 (0.0%)	2 (16.7%)	2 (5.4%)
		Worsened by 2 Categories	1 (4.0%)	0 (0.0%)	1 (2.7%)
		Worsened by 1 Category	7 (28.0%)	0 (0.0%)	7 (18.9%)
		No Change	13 (52.0%)	9 (75.0%)	22 (59.5%)
		Improved by ≥1 Categories	4 (16.0%)	1 (8.3%)	5 (13.5%)
	C16D1		N=25	N=10	N=35
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (10.0%)	1 (2.9%)
		Worsened by 1 Category	2 (8.0%)	2 (20.0%)	4 (11.4%)
		No Change	19 (76.0%)	6 (60.0%)	25 (71.4%)
		Improved by ≥1 Categories	4 (16.0%)	1 (10.0%)	5 (14.3%)
	C17D1		N=23	N=7	N=30
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	5 (21.7%)	0 (0.0%)	5 (16.7%)
		No Change	15 (65.2%)	6 (85.7%)	21 (70.0%)
		Improved by ≥1 Categories	3 (13.0%)	1 (14.3%)	4 (13.3%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (15.0%)	0 (0.0%)	3 (11.1%)
		No Change	14 (70.0%)	6 (85.7%)	20 (74.1%)
		Improved by ≥1 Categories	3 (15.0%)	1 (14.3%)	4 (14.8%)
	C19D1		N=19	N=5	N=24
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (10.5%)	2 (40.0%)	4 (16.7%)
		No Change	12 (63.2%)	2 (40.0%)	14 (58.3%)
		Improved by ≥1 Categories	5 (26.3%)	1 (20.0%)	6 (25.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C20D1		N=18	N=4	N=22
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	4 (22.2%)	0 (0.0%)	4 (18.2%)
		No Change	9 (50.0%)	3 (75.0%)	12 (54.5%)
		Improved by ≥1 Categories	5 (27.8%)	1 (25.0%)	6 (27.3%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (17.6%)	0 (0.0%)	3 (14.3%)
		No Change	12 (70.6%)	3 (75.0%)	15 (71.4%)
		Improved by ≥1 Categories	2 (11.8%)	1 (25.0%)	3 (14.3%)
	C22D1		N=14	N=3	N=17
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (21.4%)	0 (0.0%)	3 (17.6%)
		No Change	7 (50.0%)	2 (66.7%)	9 (52.9%)
		Improved by ≥1 Categories	4 (28.6%)	1 (33.3%)	5 (29.4%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (8.3%)
		No Change	4 (44.4%)	2 (66.7%)	6 (50.0%)
		Improved by ≥1 Categories	4 (44.4%)	1 (33.3%)	5 (41.7%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (9.1%)
		No Change	6 (66.7%)	1 (50.0%)	7 (63.6%)
		Improved by ≥1 Categories	2 (22.2%)	1 (50.0%)	3 (27.3%)
	C25D1		N=7	N=0	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (NE)	1 (14.3%)
		No Change	3 (42.9%)	0 (NE)	3 (42.9%)
		Improved by ≥1 Categories	3 (42.9%)	0 (NE)	3 (42.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (28.6%)	0 (0.0%)	2 (25.0%)
		No Change	4 (57.1%)	1 (100.0%)	5 (62.5%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (0.0%)	1 (12.5%)
		No Change	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (16.7%)	0 (0.0%)	1 (14.3%)
		No Change	5 (83.3%)	1 (100.0%)	6 (85.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (50.0%)	1 (100.0%)	3 (60.0%)
		Improved by ≥1 Categories	2 (50.0%)	0 (0.0%)	2 (40.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (20.0%)
		No Change	4 (100.0%)	0 (0.0%)	4 (80.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (33.3%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	1 (50.0%)	0 (0.0%)	1 (33.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	1 (50.0%)	1 (100.0%)	2 (66.7%)
		Improved by ≥1 Categories	1 (50.0%)	0 (0.0%)	1 (33.3%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (66.7%)	1 (100.0%)	3 (75.0%)
		Improved by ≥1 Categories	1 (33.3%)	0 (0.0%)	1 (25.0%)
	C34D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	EOT		N=113	N=118	N=231
		Worsened by ≥3 Categories	3 (2.7%)	5 (4.2%)	8 (3.5%)
		Worsened by 2 Categories	6 (5.3%)	6 (5.1%)	12 (5.2%)
		Worsened by 1 Category	21 (18.6%)	23 (19.5%)	44 (19.0%)
		No Change	69 (61.1%)	67 (56.8%)	136 (58.9%)
		Improved by ≥1 Categories	14 (12.4%)	17 (14.4%)	31 (13.4%)
	Long Term		N=14	N=9	N=23
	Follow-up	Worsened by ≥3 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 2 Categories	1 (7.1%)	0 (0.0%)	1 (4.3%)
		Worsened by 1 Category	2 (14.3%)	1 (11.1%)	3 (13.0%)
		No Change	9 (64.3%)	5 (55.6%)	14 (60.9%)
		Improved by ≥1 Categories	2 (14.3%)	2 (22.2%)	4 (17.4%)
Hair Loss Amount	C2D1		N=146	N=139	N=285
		Worsened by ≥3 Categories	95 (65.1%)	34 (24.5%)	129 (45.3%)
		Worsened by 2 Categories	11 (7.5%)	15 (10.8%)	26 (9.1%)
		Worsened by 1 Category	17 (11.6%)	13 (9.4%)	30 (10.5%)
		No Change	20 (13.7%)	65 (46.8%)	85 (29.8%)
		Improved by ≥1 Categories	3 (2.1%)	12 (8.6%)	15 (5.3%)
	C3D1		N=105	N=99	N=204
		Worsened by ≥3 Categories	31 (29.5%)	21 (21.2%)	52 (25.5%)
		Worsened by 2 Categories	7 (6.7%)	12 (12.1%)	19 (9.3%)
		Worsened by 1 Category	10 (9.5%)	21 (21.2%)	31 (15.2%)
		No Change	48 (45.7%)	39 (39.4%)	87 (42.6%)
		Improved by ≥1 Categories	9 (8.6%)	6 (6.1%)	15 (7.4%)
	C4D1		N=94	N=88	N=182
		Worsened by ≥3 Categories	21 (22.3%)	11 (12.5%)	32 (17.6%)
		Worsened by 2 Categories	3 (3.2%)	8 (9.1%)	11 (6.0%)
		Worsened by 1 Category	11 (11.7%)	19 (21.6%)	30 (16.5%)
		No Change	46 (48.9%)	45 (51.1%)	91 (50.0%)
		Improved by ≥1 Categories	13 (13.8%)	5 (5.7%)	18 (9.9%)
	C5D1		N=82	N=74	N=156
		Worsened by ≥3 Categories	17 (20.7%)	4 (5.4%)	21 (13.5%)
		Worsened by 2 Categories	3 (3.7%)	15 (20.3%)	18 (11.5%)
		Worsened by 1 Category	5 (6.1%)	20 (27.0%)	25 (16.0%)
		No Change	44 (53.7%)	31 (41.9%)	75 (48.1%)
		Improved by ≥1 Categories	13 (15.9%)	4 (5.4%)	17 (10.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C6D1		N=80	N=66	N=146
		Worsened by ≥3 Categories	15 (18.8%)	4 (6.1%)	19 (13.0%)
		Worsened by 2 Categories	5 (6.3%)	6 (9.1%)	11 (7.5%)
		Worsened by 1 Category	5 (6.3%)	18 (27.3%)	23 (15.8%)
		No Change	42 (52.5%)	35 (53.0%)	77 (52.7%)
		Improved by ≥1 Categories	13 (16.3%)	3 (4.5%)	16 (11.0%)
	C7D1		N=67	N=53	N=120
		Worsened by ≥3 Categories	11 (16.4%)	1 (1.9%)	12 (10.0%)
		Worsened by 2 Categories	2 (3.0%)	4 (7.5%)	6 (5.0%)
		Worsened by 1 Category	3 (4.5%)	12 (22.6%)	15 (12.5%)
		No Change	40 (59.7%)	34 (64.2%)	74 (61.7%)
		Improved by ≥1 Categories	11 (16.4%)	2 (3.8%)	13 (10.8%)
	C8D1		N=60	N=48	N=108
		Worsened by ≥3 Categories	12 (20.0%)	0 (0.0%)	12 (11.1%)
		Worsened by 2 Categories	2 (3.3%)	1 (2.1%)	3 (2.8%)
		Worsened by 1 Category	3 (5.0%)	14 (29.2%)	17 (15.7%)
		No Change	37 (61.7%)	29 (60.4%)	66 (61.1%)
		Improved by ≥1 Categories	6 (10.0%)	4 (8.3%)	10 (9.3%)
	C9D1		N=47	N=40	N=87
		Worsened by ≥3 Categories	6 (12.8%)	1 (2.5%)	7 (8.0%)
		Worsened by 2 Categories	1 (2.1%)	3 (7.5%)	4 (4.6%)
		Worsened by 1 Category	4 (8.5%)	11 (27.5%)	15 (17.2%)
		No Change	31 (66.0%)	23 (57.5%)	54 (62.1%)
		Improved by ≥1 Categories	5 (10.6%)	2 (5.0%)	7 (8.0%)
	C10D1		N=38	N=29	N=67
		Worsened by ≥3 Categories	5 (13.2%)	0 (0.0%)	5 (7.5%)
		Worsened by 2 Categories	1 (2.6%)	2 (6.9%)	3 (4.5%)
		Worsened by 1 Category	1 (2.6%)	8 (27.6%)	9 (13.4%)
		No Change	27 (71.1%)	18 (62.1%)	45 (67.2%)
		Improved by ≥1 Categories	4 (10.5%)	1 (3.4%)	5 (7.5%)
	C11D1		N=32	N=23	N=55
		Worsened by ≥3 Categories	4 (12.5%)	0 (0.0%)	4 (7.3%)
		Worsened by 2 Categories	1 (3.1%)	0 (0.0%)	1 (1.8%)
		Worsened by 1 Category	2 (6.3%)	4 (17.4%)	6 (10.9%)
		No Change	23 (71.9%)	17 (73.9%)	40 (72.7%)
		Improved by ≥1 Categories	2 (6.3%)	2 (8.7%)	4 (7.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C12D1		N=34	N=18	N=52
		Worsened by ≥3 Categories	5 (14.7%)	0 (0.0%)	5 (9.6%)
		Worsened by 2 Categories	1 (2.9%)	0 (0.0%)	1 (1.9%)
		Worsened by 1 Category	2 (5.9%)	7 (38.9%)	9 (17.3%)
		No Change	25 (73.5%)	10 (55.6%)	35 (67.3%)
		Improved by ≥1 Categories	1 (2.9%)	1 (5.6%)	2 (3.8%)
	C13D1		N=25	N=13	N=38
		Worsened by ≥3 Categories	4 (16.0%)	0 (0.0%)	4 (10.5%)
		Worsened by 2 Categories	1 (4.0%)	0 (0.0%)	1 (2.6%)
		Worsened by 1 Category	1 (4.0%)	4 (30.8%)	5 (13.2%)
		No Change	17 (68.0%)	8 (61.5%)	25 (65.8%)
		Improved by ≥1 Categories	2 (8.0%)	1 (7.7%)	3 (7.9%)
	C14D1		N=24	N=11	N=35
		Worsened by ≥3 Categories	6 (25.0%)	0 (0.0%)	6 (17.1%)
		Worsened by 2 Categories	2 (8.3%)	0 (0.0%)	2 (5.7%)
		Worsened by 1 Category	0 (0.0%)	3 (27.3%)	3 (8.6%)
		No Change	15 (62.5%)	7 (63.6%)	22 (62.9%)
		Improved by ≥1 Categories	1 (4.2%)	1 (9.1%)	2 (5.7%)
	C15D1		N=21	N=11	N=32
		Worsened by ≥3 Categories	4 (19.0%)	0 (0.0%)	4 (12.5%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (4.8%)	3 (27.3%)	4 (12.5%)
		No Change	15 (71.4%)	7 (63.6%)	22 (68.8%)
		Improved by ≥1 Categories	1 (4.8%)	1 (9.1%)	2 (6.3%)
	C16D1		N=21	N=8	N=29
		Worsened by ≥3 Categories	3 (14.3%)	0 (0.0%)	3 (10.3%)
		Worsened by 2 Categories	1 (4.8%)	0 (0.0%)	1 (3.4%)
		Worsened by 1 Category	1 (4.8%)	3 (37.5%)	4 (13.8%)
		No Change	16 (76.2%)	5 (62.5%)	21 (72.4%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C17D1		N=21	N=6	N=27
		Worsened by ≥3 Categories	3 (14.3%)	1 (16.7%)	4 (14.8%)
		Worsened by 2 Categories	1 (4.8%)	0 (0.0%)	1 (3.7%)
		Worsened by 1 Category	1 (4.8%)	2 (33.3%)	3 (11.1%)
		No Change	15 (71.4%)	3 (50.0%)	18 (66.7%)
		Improved by ≥1 Categories	1 (4.8%)	0 (0.0%)	1 (3.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C18D1		N=16	N=7	N=23
		Worsened by ≥3 Categories	4 (25.0%)	0 (0.0%)	4 (17.4%)
		Worsened by 2 Categories	1 (6.3%)	0 (0.0%)	1 (4.3%)
		Worsened by 1 Category	0 (0.0%)	2 (28.6%)	2 (8.7%)
		No Change	10 (62.5%)	5 (71.4%)	15 (65.2%)
		Improved by ≥1 Categories	1 (6.3%)	0 (0.0%)	1 (4.3%)
	C19D1		N=16	N=6	N=22
		Worsened by ≥3 Categories	4 (25.0%)	0 (0.0%)	4 (18.2%)
		Worsened by 2 Categories	1 (6.3%)	0 (0.0%)	1 (4.5%)
		Worsened by 1 Category	1 (6.3%)	1 (16.7%)	2 (9.1%)
		No Change	9 (56.3%)	5 (83.3%)	14 (63.6%)
		Improved by ≥1 Categories	1 (6.3%)	0 (0.0%)	1 (4.5%)
	C20D1		N=15	N=4	N=19
		Worsened by ≥3 Categories	3 (20.0%)	0 (0.0%)	3 (15.8%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (6.7%)	1 (25.0%)	2 (10.5%)
		No Change	10 (66.7%)	3 (75.0%)	13 (68.4%)
		Improved by ≥1 Categories	1 (6.7%)	0 (0.0%)	1 (5.3%)
	C21D1		N=14	N=4	N=18
		Worsened by ≥3 Categories	4 (28.6%)	0 (0.0%)	4 (22.2%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (25.0%)	1 (5.6%)
		No Change	9 (64.3%)	3 (75.0%)	12 (66.7%)
		Improved by ≥1 Categories	1 (7.1%)	0 (0.0%)	1 (5.6%)
	C22D1		N=11	N=3	N=14
		Worsened by ≥3 Categories	3 (27.3%)	0 (0.0%)	3 (21.4%)
		Worsened by 2 Categories	1 (9.1%)	0 (0.0%)	1 (7.1%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (54.5%)	3 (100.0%)	9 (64.3%)
		Improved by ≥1 Categories	1 (9.1%)	0 (0.0%)	1 (7.1%)
	C23D1		N=8	N=3	N=11
		Worsened by ≥3 Categories	2 (25.0%)	0 (0.0%)	2 (18.2%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (62.5%)	3 (100.0%)	8 (72.7%)
		Improved by ≥1 Categories	1 (12.5%)	0 (0.0%)	1 (9.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C24D1		N=8	N=2	N=10
		Worsened by ≥3 Categories	1 (12.5%)	0 (0.0%)	1 (10.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (75.0%)	2 (100.0%)	8 (80.0%)
		Improved by ≥1 Categories	1 (12.5%)	0 (0.0%)	1 (10.0%)
	C25D1		N=7	N=0	N=7
		Worsened by ≥3 Categories	1 (14.3%)	0 (NE)	1 (14.3%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	5 (71.4%)	0 (NE)	5 (71.4%)
		Improved by ≥1 Categories	1 (14.3%)	0 (NE)	1 (14.3%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (0.0%)	1 (12.5%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C27D1		N=5	N=1	N=6
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (100.0%)	1 (100.0%)	6 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C28D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	4 (100.0%)	1 (100.0%)	5 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C30D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (100.0%)	1 (100.0%)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	3 (100.0%)	1 (100.0%)	4 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C36D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=104	N=117	N=221
		Worsened by ≥3 Categories	26 (25.0%)	10 (8.5%)	36 (16.3%)
		Worsened by 2 Categories	5 (4.8%)	8 (6.8%)	13 (5.9%)
		Worsened by 1 Category	5 (4.8%)	23 (19.7%)	28 (12.7%)
		No Change	56 (53.8%)	71 (60.7%)	127 (57.5%)
		Improved by ≥1 Categories	12 (11.5%)	5 (4.3%)	17 (7.7%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	1 (7.1%)	1 (11.1%)	2 (8.7%)
		Worsened by 2 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 1 Category	0 (0.0%)	1 (11.1%)	1 (4.3%)
		No Change	11 (78.6%)	6 (66.7%)	17 (73.9%)
		Improved by ≥1 Categories	2 (14.3%)	0 (0.0%)	2 (8.7%)
Fatigue Severity	C2D1		N=148	N=143	N=291
		Worsened by ≥3 Categories	2 (1.4%)	2 (1.4%)	4 (1.4%)
		Worsened by 2 Categories	16 (10.8%)	10 (7.0%)	26 (8.9%)
		Worsened by 1 Category	46 (31.1%)	48 (33.6%)	94 (32.3%)
		No Change	64 (43.2%)	59 (41.3%)	123 (42.3%)
		Improved by ≥1 Categories	20 (13.5%)	24 (16.8%)	44 (15.1%)
	C3D1		N=115	N=102	N=217
		Worsened by ≥3 Categories	1 (0.9%)	1 (1.0%)	2 (0.9%)
		Worsened by 2 Categories	9 (7.8%)	7 (6.9%)	16 (7.4%)
		Worsened by 1 Category	30 (26.1%)	23 (22.5%)	53 (24.4%)
		No Change	57 (49.6%)	51 (50.0%)	108 (49.8%)
		Improved by ≥1 Categories	18 (15.7%)	20 (19.6%)	38 (17.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C4D1		N=106	N=93	N=199
		Worsened by ≥3 Categories	1 (0.9%)	0 (0.0%)	1 (0.5%)
		Worsened by 2 Categories	7 (6.6%)	6 (6.5%)	13 (6.5%)
		Worsened by 1 Category	26 (24.5%)	22 (23.7%)	48 (24.1%)
		No Change	45 (42.5%)	40 (43.0%)	85 (42.7%)
		Improved by ≥1 Categories	27 (25.5%)	25 (26.9%)	52 (26.1%)
	C5D1		N=91	N=79	N=170
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	6 (6.6%)	2 (2.5%)	8 (4.7%)
		Worsened by 1 Category	16 (17.6%)	21 (26.6%)	37 (21.8%)
		No Change	47 (51.6%)	35 (44.3%)	82 (48.2%)
		Improved by ≥1 Categories	22 (24.2%)	21 (26.6%)	43 (25.3%)
	C6D1		N=90	N=70	N=160
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (2.2%)	2 (2.9%)	4 (2.5%)
		Worsened by 1 Category	19 (21.1%)	18 (25.7%)	37 (23.1%)
		No Change	51 (56.7%)	30 (42.9%)	81 (50.6%)
		Improved by ≥1 Categories	18 (20.0%)	20 (28.6%)	38 (23.8%)
	C7D1		N=74	N=52	N=126
		Worsened by ≥3 Categories	1 (1.4%)	0 (0.0%)	1 (0.8%)
		Worsened by 2 Categories	2 (2.7%)	1 (1.9%)	3 (2.4%)
		Worsened by 1 Category	8 (10.8%)	7 (13.5%)	15 (11.9%)
		No Change	45 (60.8%)	30 (57.7%)	75 (59.5%)
		Improved by ≥1 Categories	18 (24.3%)	14 (26.9%)	32 (25.4%)
	C8D1		N=70	N=50	N=120
		Worsened by ≥3 Categories	1 (1.4%)	0 (0.0%)	1 (0.8%)
		Worsened by 2 Categories	2 (2.9%)	3 (6.0%)	5 (4.2%)
		Worsened by 1 Category	10 (14.3%)	8 (16.0%)	18 (15.0%)
		No Change	35 (50.0%)	26 (52.0%)	61 (50.8%)
		Improved by ≥1 Categories	22 (31.4%)	13 (26.0%)	35 (29.2%)
	C9D1		N=57	N=41	N=98
		Worsened by ≥3 Categories	1 (1.8%)	2 (4.9%)	3 (3.1%)
		Worsened by 2 Categories	4 (7.0%)	3 (7.3%)	7 (7.1%)
		Worsened by 1 Category	7 (12.3%)	4 (9.8%)	11 (11.2%)
		No Change	28 (49.1%)	20 (48.8%)	48 (49.0%)
		Improved by ≥1 Categories	17 (29.8%)	12 (29.3%)	29 (29.6%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C10D1		N=49	N=30	N=79
		Worsened by ≥3 Categories	0 (0.0%)	1 (3.3%)	1 (1.3%)
		Worsened by 2 Categories	0 (0.0%)	3 (10.0%)	3 (3.8%)
		Worsened by 1 Category	10 (20.4%)	5 (16.7%)	15 (19.0%)
		No Change	24 (49.0%)	14 (46.7%)	38 (48.1%)
		Improved by ≥1 Categories	15 (30.6%)	7 (23.3%)	22 (27.8%)
	C11D1		N=43	N=23	N=66
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (4.7%)	2 (8.7%)	4 (6.1%)
		Worsened by 1 Category	8 (18.6%)	3 (13.0%)	11 (16.7%)
		No Change	18 (41.9%)	12 (52.2%)	30 (45.5%)
		Improved by ≥1 Categories	15 (34.9%)	6 (26.1%)	21 (31.8%)
	C12D1		N=39	N=19	N=58
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.6%)	1 (5.3%)	2 (3.4%)
		Worsened by 1 Category	7 (17.9%)	2 (10.5%)	9 (15.5%)
		No Change	17 (43.6%)	11 (57.9%)	28 (48.3%)
		Improved by ≥1 Categories	14 (35.9%)	5 (26.3%)	19 (32.8%)
	C13D1		N=31	N=14	N=45
		Worsened by ≥3 Categories	1 (3.2%)	1 (7.1%)	2 (4.4%)
		Worsened by 2 Categories	0 (0.0%)	1 (7.1%)	1 (2.2%)
		Worsened by 1 Category	4 (12.9%)	1 (7.1%)	5 (11.1%)
		No Change	17 (54.8%)	4 (28.6%)	21 (46.7%)
		Improved by ≥1 Categories	9 (29.0%)	7 (50.0%)	16 (35.6%)
	C14D1		N=31	N=12	N=43
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (6.5%)	2 (16.7%)	4 (9.3%)
		Worsened by 1 Category	6 (19.4%)	2 (16.7%)	8 (18.6%)
		No Change	16 (51.6%)	5 (41.7%)	21 (48.8%)
		Improved by ≥1 Categories	7 (22.6%)	3 (25.0%)	10 (23.3%)
	C15D1		N=26	N=13	N=39
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	3 (23.1%)	3 (7.7%)
		Worsened by 1 Category	7 (26.9%)	2 (15.4%)	9 (23.1%)
		No Change	13 (50.0%)	5 (38.5%)	18 (46.2%)
		Improved by ≥1 Categories	6 (23.1%)	3 (23.1%)	9 (23.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C16D1		N=26	N=10	N=36
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (3.8%)	2 (20.0%)	3 (8.3%)
		Worsened by 1 Category	7 (26.9%)	1 (10.0%)	8 (22.2%)
		No Change	10 (38.5%)	2 (20.0%)	12 (33.3%)
		Improved by ≥1 Categories	8 (30.8%)	5 (50.0%)	13 (36.1%)
	C17D1		N=24	N=7	N=31
		Worsened by ≥3 Categories	0 (0.0%)	1 (14.3%)	1 (3.2%)
		Worsened by 2 Categories	0 (0.0%)	1 (14.3%)	1 (3.2%)
		Worsened by 1 Category	3 (12.5%)	1 (14.3%)	4 (12.9%)
		No Change	17 (70.8%)	1 (14.3%)	18 (58.1%)
		Improved by ≥1 Categories	4 (16.7%)	3 (42.9%)	7 (22.6%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	2 (28.6%)	2 (7.4%)
		Worsened by 1 Category	1 (5.0%)	0 (0.0%)	1 (3.7%)
		No Change	13 (65.0%)	2 (28.6%)	15 (55.6%)
		Improved by ≥1 Categories	6 (30.0%)	3 (42.9%)	9 (33.3%)
	C19D1		N=19	N=6	N=25
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (16.7%)	1 (4.0%)
		Worsened by 1 Category	1 (5.3%)	1 (16.7%)	2 (8.0%)
		No Change	12 (63.2%)	3 (50.0%)	15 (60.0%)
		Improved by ≥1 Categories	6 (31.6%)	1 (16.7%)	7 (28.0%)
	C20D1		N=19	N=4	N=23
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (5.3%)	0 (0.0%)	1 (4.3%)
		Worsened by 1 Category	3 (15.8%)	2 (50.0%)	5 (21.7%)
		No Change	10 (52.6%)	1 (25.0%)	11 (47.8%)
		Improved by ≥1 Categories	5 (26.3%)	1 (25.0%)	6 (26.1%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (25.0%)	1 (4.8%)
		Worsened by 1 Category	2 (11.8%)	1 (25.0%)	3 (14.3%)
		No Change	11 (64.7%)	1 (25.0%)	12 (57.1%)
		Improved by ≥1 Categories	4 (23.5%)	1 (25.0%)	5 (23.8%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (6.7%)	1 (33.3%)	2 (11.1%)
		No Change	10 (66.7%)	1 (33.3%)	11 (61.1%)
		Improved by ≥1 Categories	4 (26.7%)	1 (33.3%)	5 (27.8%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (33.3%)	1 (33.3%)	4 (33.3%)
		No Change	4 (44.4%)	0 (0.0%)	4 (33.3%)
		Improved by ≥1 Categories	2 (22.2%)	2 (66.7%)	4 (33.3%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (11.1%)	0 (0.0%)	1 (9.1%)
		No Change	6 (66.7%)	1 (50.0%)	7 (63.6%)
		Improved by ≥1 Categories	2 (22.2%)	1 (50.0%)	3 (27.3%)
	C25D1		N=8	N=0	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (12.5%)	0 (NE)	1 (12.5%)
		No Change	4 (50.0%)	0 (NE)	4 (50.0%)
		Improved by ≥1 Categories	3 (37.5%)	0 (NE)	3 (37.5%)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (0.0%)	1 (12.5%)
		No Change	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	6 (85.7%)	1 (100.0%)	7 (87.5%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (16.7%)	0 (0.0%)	1 (14.3%)
		No Change	4 (66.7%)	1 (100.0%)	5 (71.4%)
		Improved by ≥1 Categories	1 (16.7%)	0 (0.0%)	1 (14.3%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (25.0%)	1 (100.0%)	2 (40.0%)
		No Change	2 (50.0%)	0 (0.0%)	2 (40.0%)
		Improved by ≥1 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (25.0%)	1 (100.0%)	2 (40.0%)
		No Change	3 (75.0%)	0 (0.0%)	3 (60.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (33.3%)
		No Change	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Worsened by 1 Category	1 (50.0%)	0 (0.0%)	1 (33.3%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (25.0%)
		No Change	3 (100.0%)	0 (0.0%)	3 (75.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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	C34D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=3	N=0	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	3 (100.0%)	0 (NE)	3 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C38D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	1 (50.0%)	0 (NE)	1 (50.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	0 (0.0%)	0 (NE)	0 (0.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	EOT		N=122	N=125	N=247
		Worsened by ≥3 Categories	5 (4.1%)	2 (1.6%)	7 (2.8%)
		Worsened by 2 Categories	14 (11.5%)	16 (12.8%)	30 (12.1%)
		Worsened by 1 Category	28 (23.0%)	35 (28.0%)	63 (25.5%)
		No Change	54 (44.3%)	50 (40.0%)	104 (42.1%)
		Improved by ≥1 Categories	21 (17.2%)	22 (17.6%)	43 (17.4%)
	Long Term Follow-up		N=14	N=9	N=23
		Worsened by ≥3 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 2 Categories	2 (14.3%)	1 (11.1%)	3 (13.0%)
		Worsened by 1 Category	4 (28.6%)	4 (44.4%)	8 (34.8%)
		No Change	5 (35.7%)	3 (33.3%)	8 (34.8%)
		Improved by ≥1 Categories	3 (21.4%)	0 (0.0%)	3 (13.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
Fatigue Interference	C2D1		N=145	N=139	N=284
		Worsened by ≥3 Categories	5 (3.4%)	4 (2.9%)	9 (3.2%)
		Worsened by 2 Categories	11 (7.6%)	12 (8.6%)	23 (8.1%)
		Worsened by 1 Category	46 (31.7%)	36 (25.9%)	82 (28.9%)
		No Change	59 (40.7%)	60 (43.2%)	119 (41.9%)
		Improved by ≥1 Categories	24 (16.6%)	27 (19.4%)	51 (18.0%)
	C3D1		N=115	N=101	N=216
		Worsened by ≥3 Categories	4 (3.5%)	3 (3.0%)	7 (3.2%)
		Worsened by 2 Categories	5 (4.3%)	4 (4.0%)	9 (4.2%)
		Worsened by 1 Category	25 (21.7%)	23 (22.8%)	48 (22.2%)
		No Change	59 (51.3%)	42 (41.6%)	101 (46.8%)
		Improved by ≥1 Categories	22 (19.1%)	29 (28.7%)	51 (23.6%)
	C4D1		N=105	N=92	N=197
		Worsened by ≥3 Categories	2 (1.9%)	1 (1.1%)	3 (1.5%)
		Worsened by 2 Categories	8 (7.6%)	9 (9.8%)	17 (8.6%)
		Worsened by 1 Category	24 (22.9%)	18 (19.6%)	42 (21.3%)
		No Change	43 (41.0%)	34 (37.0%)	77 (39.1%)
		Improved by ≥1 Categories	28 (26.7%)	30 (32.6%)	58 (29.4%)
	C5D1		N=85	N=76	N=161
		Worsened by ≥3 Categories	2 (2.4%)	0 (0.0%)	2 (1.2%)
		Worsened by 2 Categories	9 (10.6%)	4 (5.3%)	13 (8.1%)
		Worsened by 1 Category	8 (9.4%)	15 (19.7%)	23 (14.3%)
		No Change	44 (51.8%)	39 (51.3%)	83 (51.6%)
		Improved by ≥1 Categories	22 (25.9%)	18 (23.7%)	40 (24.8%)
	C6D1		N=86	N=69	N=155
		Worsened by ≥3 Categories	1 (1.2%)	1 (1.4%)	2 (1.3%)
		Worsened by 2 Categories	5 (5.8%)	6 (8.7%)	11 (7.1%)
		Worsened by 1 Category	18 (20.9%)	10 (14.5%)	28 (18.1%)
		No Change	39 (45.3%)	38 (55.1%)	77 (49.7%)
		Improved by ≥1 Categories	23 (26.7%)	14 (20.3%)	37 (23.9%)
	C7D1		N=73	N=48	N=121
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	5 (6.8%)	1 (2.1%)	6 (5.0%)
		Worsened by 1 Category	9 (12.3%)	10 (20.8%)	19 (15.7%)
		No Change	35 (47.9%)	20 (41.7%)	55 (45.5%)
		Improved by ≥1 Categories	24 (32.9%)	17 (35.4%)	41 (33.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C8D1		N=69	N=49	N=118
		Worsened by ≥3 Categories	1 (1.4%)	0 (0.0%)	1 (0.8%)
		Worsened by 2 Categories	2 (2.9%)	5 (10.2%)	7 (5.9%)
		Worsened by 1 Category	13 (18.8%)	6 (12.2%)	19 (16.1%)
		No Change	27 (39.1%)	25 (51.0%)	52 (44.1%)
		Improved by ≥1 Categories	26 (37.7%)	13 (26.5%)	39 (33.1%)
	C9D1		N=55	N=39	N=94
		Worsened by ≥3 Categories	1 (1.8%)	0 (0.0%)	1 (1.1%)
		Worsened by 2 Categories	3 (5.5%)	4 (10.3%)	7 (7.4%)
		Worsened by 1 Category	11 (20.0%)	9 (23.1%)	20 (21.3%)
		No Change	22 (40.0%)	16 (41.0%)	38 (40.4%)
		Improved by ≥1 Categories	18 (32.7%)	10 (25.6%)	28 (29.8%)
	C10D1		N=47	N=28	N=75
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (4.3%)	6 (21.4%)	8 (10.7%)
		Worsened by 1 Category	8 (17.0%)	2 (7.1%)	10 (13.3%)
		No Change	20 (42.6%)	12 (42.9%)	32 (42.7%)
		Improved by ≥1 Categories	17 (36.2%)	8 (28.6%)	25 (33.3%)
	C11D1		N=40	N=23	N=63
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (2.5%)	2 (8.7%)	3 (4.8%)
		Worsened by 1 Category	10 (25.0%)	5 (21.7%)	15 (23.8%)
		No Change	14 (35.0%)	7 (30.4%)	21 (33.3%)
		Improved by ≥1 Categories	15 (37.5%)	9 (39.1%)	24 (38.1%)
	C12D1		N=35	N=19	N=54
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (5.7%)	1 (5.3%)	3 (5.6%)
		Worsened by 1 Category	4 (11.4%)	2 (10.5%)	6 (11.1%)
		No Change	16 (45.7%)	11 (57.9%)	27 (50.0%)
		Improved by ≥1 Categories	13 (37.1%)	5 (26.3%)	18 (33.3%)
	C13D1		N=30	N=14	N=44
		Worsened by ≥3 Categories	1 (3.3%)	1 (7.1%)	2 (4.5%)
		Worsened by 2 Categories	0 (0.0%)	1 (7.1%)	1 (2.3%)
		Worsened by 1 Category	7 (23.3%)	0 (0.0%)	7 (15.9%)
		No Change	13 (43.3%)	6 (42.9%)	19 (43.2%)
		Improved by ≥1 Categories	9 (30.0%)	6 (42.9%)	15 (34.1%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C14D1		N=29	N=12	N=41
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (6.9%)	2 (16.7%)	4 (9.8%)
		Worsened by 1 Category	4 (13.8%)	0 (0.0%)	4 (9.8%)
		No Change	16 (55.2%)	7 (58.3%)	23 (56.1%)
		Improved by ≥1 Categories	7 (24.1%)	3 (25.0%)	10 (24.4%)
	C15D1		N=25	N=13	N=38
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	2 (8.0%)	2 (15.4%)	4 (10.5%)
		Worsened by 1 Category	6 (24.0%)	3 (23.1%)	9 (23.7%)
		No Change	11 (44.0%)	3 (23.1%)	14 (36.8%)
		Improved by ≥1 Categories	6 (24.0%)	5 (38.5%)	11 (28.9%)
	C16D1		N=25	N=10	N=35
		Worsened by ≥3 Categories	1 (4.0%)	0 (0.0%)	1 (2.9%)
		Worsened by 2 Categories	0 (0.0%)	2 (20.0%)	2 (5.7%)
		Worsened by 1 Category	6 (24.0%)	1 (10.0%)	7 (20.0%)
		No Change	8 (32.0%)	4 (40.0%)	12 (34.3%)
		Improved by ≥1 Categories	10 (40.0%)	3 (30.0%)	13 (37.1%)
	C17D1		N=22	N=7	N=29
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (14.3%)	1 (3.4%)
		Worsened by 1 Category	5 (22.7%)	1 (14.3%)	6 (20.7%)
		No Change	12 (54.5%)	2 (28.6%)	14 (48.3%)
		Improved by ≥1 Categories	5 (22.7%)	3 (42.9%)	8 (27.6%)
	C18D1		N=20	N=7	N=27
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (14.3%)	1 (3.7%)
		Worsened by 1 Category	3 (15.0%)	1 (14.3%)	4 (14.8%)
		No Change	10 (50.0%)	2 (28.6%)	12 (44.4%)
		Improved by ≥1 Categories	7 (35.0%)	3 (42.9%)	10 (37.0%)
	C19D1		N=19	N=5	N=24
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (20.0%)	1 (4.2%)
		Worsened by 1 Category	3 (15.8%)	1 (20.0%)	4 (16.7%)
		No Change	10 (52.6%)	1 (20.0%)	11 (45.8%)
		Improved by ≥1 Categories	6 (31.6%)	2 (40.0%)	8 (33.3%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C20D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (25.0%)	1 (4.8%)
		Worsened by 1 Category	5 (29.4%)	0 (0.0%)	5 (23.8%)
		No Change	8 (47.1%)	2 (50.0%)	10 (47.6%)
		Improved by ≥1 Categories	4 (23.5%)	1 (25.0%)	5 (23.8%)
	C21D1		N=17	N=4	N=21
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (25.0%)	1 (4.8%)
		Worsened by 1 Category	4 (23.5%)	1 (25.0%)	5 (23.8%)
		No Change	7 (41.2%)	1 (25.0%)	8 (38.1%)
		Improved by ≥1 Categories	6 (35.3%)	1 (25.0%)	7 (33.3%)
	C22D1		N=15	N=3	N=18
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	3 (20.0%)	1 (33.3%)	4 (22.2%)
		No Change	5 (33.3%)	1 (33.3%)	6 (33.3%)
		Improved by ≥1 Categories	7 (46.7%)	1 (33.3%)	8 (44.4%)
	C23D1		N=9	N=3	N=12
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (22.2%)	1 (33.3%)	3 (25.0%)
		No Change	4 (44.4%)	1 (33.3%)	5 (41.7%)
		Improved by ≥1 Categories	3 (33.3%)	1 (33.3%)	4 (33.3%)
	C24D1		N=9	N=2	N=11
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	2 (22.2%)	0 (0.0%)	2 (18.2%)
		No Change	6 (66.7%)	1 (50.0%)	7 (63.6%)
		Improved by ≥1 Categories	1 (11.1%)	1 (50.0%)	2 (18.2%)
	C25D1		N=7	N=0	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (NE)	1 (14.3%)
		No Change	3 (42.9%)	0 (NE)	3 (42.9%)
		Improved by ≥1 Categories	3 (42.9%)	0 (NE)	3 (42.9%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C26D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C27D1		N=7	N=1	N=8
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	1 (14.3%)	0 (0.0%)	1 (12.5%)
		No Change	5 (71.4%)	1 (100.0%)	6 (75.0%)
		Improved by ≥1 Categories	1 (14.3%)	0 (0.0%)	1 (12.5%)
	C28D1		N=6	N=1	N=7
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	5 (83.3%)	1 (100.0%)	6 (85.7%)
		Improved by ≥1 Categories	1 (16.7%)	0 (0.0%)	1 (14.3%)
	C29D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (25.0%)	1 (100.0%)	2 (40.0%)
		Worsened by 1 Category	0 (0.0%)	0 (0.0%)	0 (0.0%)
		No Change	2 (50.0%)	0 (0.0%)	2 (40.0%)
		Improved by ≥1 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
	C30D1		N=4	N=1	N=5
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	1 (25.0%)	0 (0.0%)	1 (20.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (20.0%)
		No Change	3 (75.0%)	0 (0.0%)	3 (60.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C31D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (33.3%)
		No Change	2 (100.0%)	0 (0.0%)	2 (66.7%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C32D1		N=2	N=1	N=3
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	1 (100.0%)	1 (33.3%)
		Worsened by 1 Category	1 (50.0%)	0 (0.0%)	1 (33.3%)
		No Change	1 (50.0%)	0 (0.0%)	1 (33.3%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C33D1		N=3	N=1	N=4
		Worsened by ≥3 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	1 (100.0%)	1 (25.0%)
		No Change	3 (100.0%)	0 (0.0%)	3 (75.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (0.0%)	0 (0.0%)
	C34D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C35D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	1 (50.0%)	0 (NE)	1 (50.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C36D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C37D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
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Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	C38D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C39D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C40D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	2 (100.0%)	0 (NE)	2 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C41D1		N=2	N=0	N=2
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	1 (50.0%)	0 (NE)	1 (50.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (50.0%)	0 (NE)	1 (50.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C42D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
	C43D1		N=1	N=0	N=1
		Worsened by ≥3 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 2 Categories	0 (0.0%)	0 (NE)	0 (0.0%)
		Worsened by 1 Category	0 (0.0%)	0 (NE)	0 (0.0%)
		No Change	1 (100.0%)	0 (NE)	1 (100.0%)
		Improved by ≥1 Categories	0 (0.0%)	0 (NE)	0 (0.0%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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Table 15.15.5
Distribution of Change in Response Categories from Baseline for PRO-CTCAE Items
Safety Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Item	Visit	Response Level	SG (N=201)	TPC (N=194)	Overall (N=395)
	EOT		N=114	N=122	N=236
		Worsened by ≥3 Categories	6 (5.3%)	5 (4.1%)	11 (4.7%)
		Worsened by 2 Categories	13 (11.4%)	12 (9.8%)	25 (10.6%)
		Worsened by 1 Category	30 (26.3%)	31 (25.4%)	61 (25.8%)
		No Change	50 (43.9%)	54 (44.3%)	104 (44.1%)
		Improved by ≥1 Categories	15 (13.2%)	20 (16.4%)	35 (14.8%)
	Long Term		N=14	N=9	N=23
	Follow-up	Worsened by ≥3 Categories	0 (0.0%)	1 (11.1%)	1 (4.3%)
		Worsened by 2 Categories	2 (14.3%)	1 (11.1%)	3 (13.0%)
		Worsened by 1 Category	2 (14.3%)	4 (44.4%)	6 (26.1%)
		No Change	6 (42.9%)	2 (22.2%)	8 (34.8%)
		Improved by ≥1 Categories	4 (28.6%)	1 (11.1%)	5 (21.7%)

Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of Safety Population subjects with non-missing scores at both baseline and at least one post-baseline visit (including the EOT visit). PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; NE = Not Estimable; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
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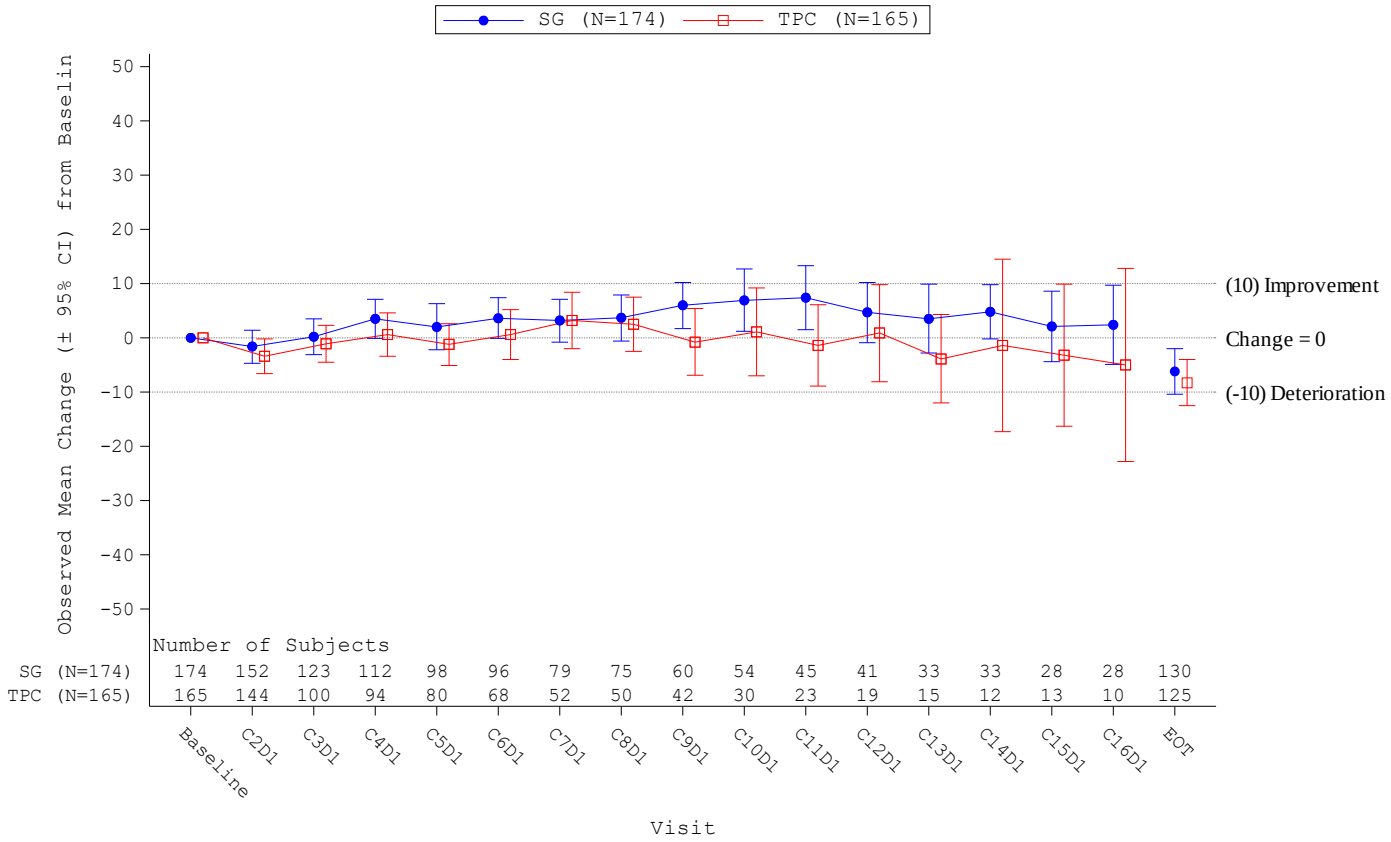
Figure 15.15.1.1.1
Observed Mean Change from Baseline in EORTC QLQ-C30 Global Health Status/QoL by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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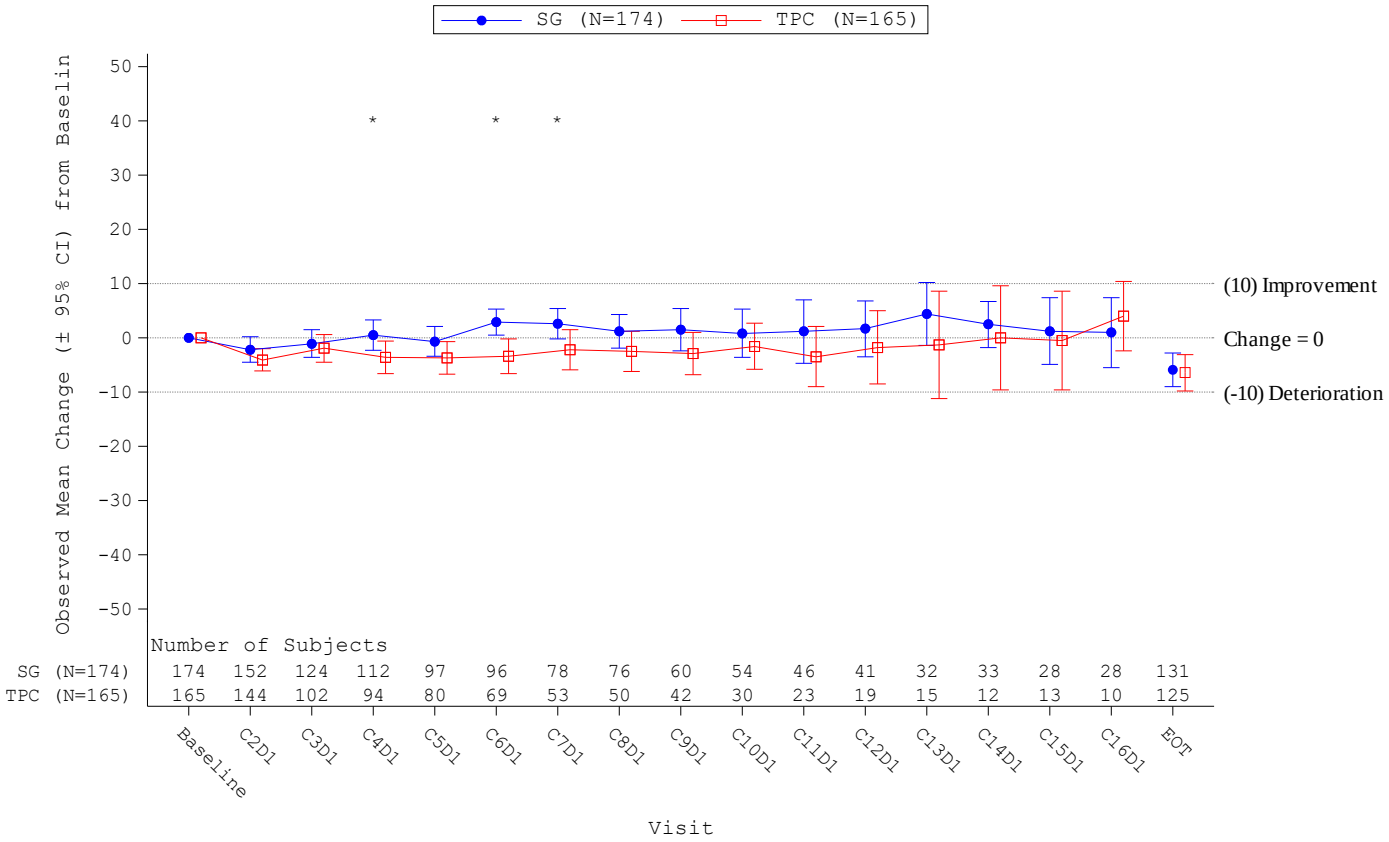
Figure 15.15.1.1.2
Observed Mean Change from Baseline in EORTC QLQ-C30 Physical Functioning by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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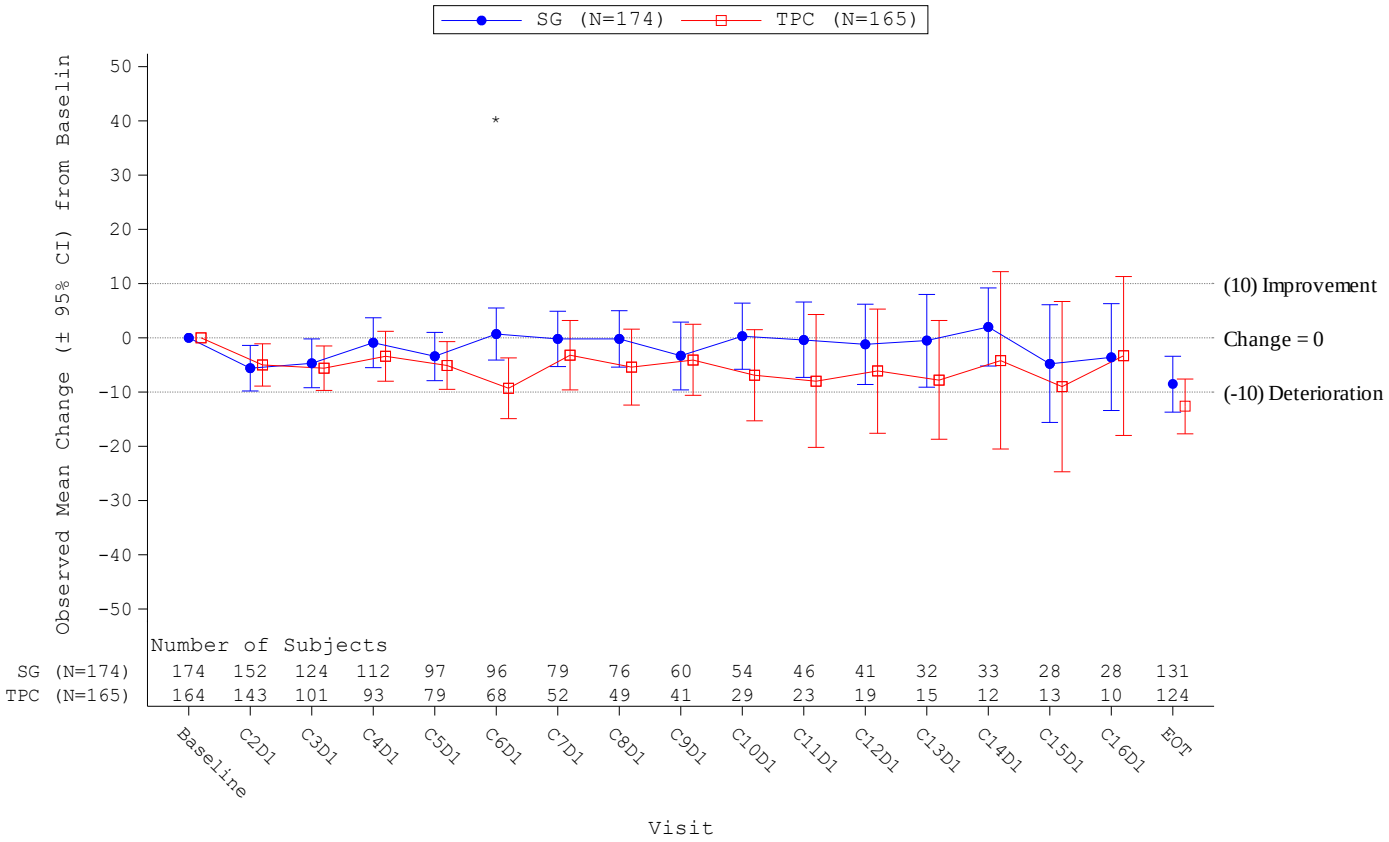
Figure 15.15.1.1.3
Observed Mean Change from Baseline in EORTC QLQ-C30 Role Functioning by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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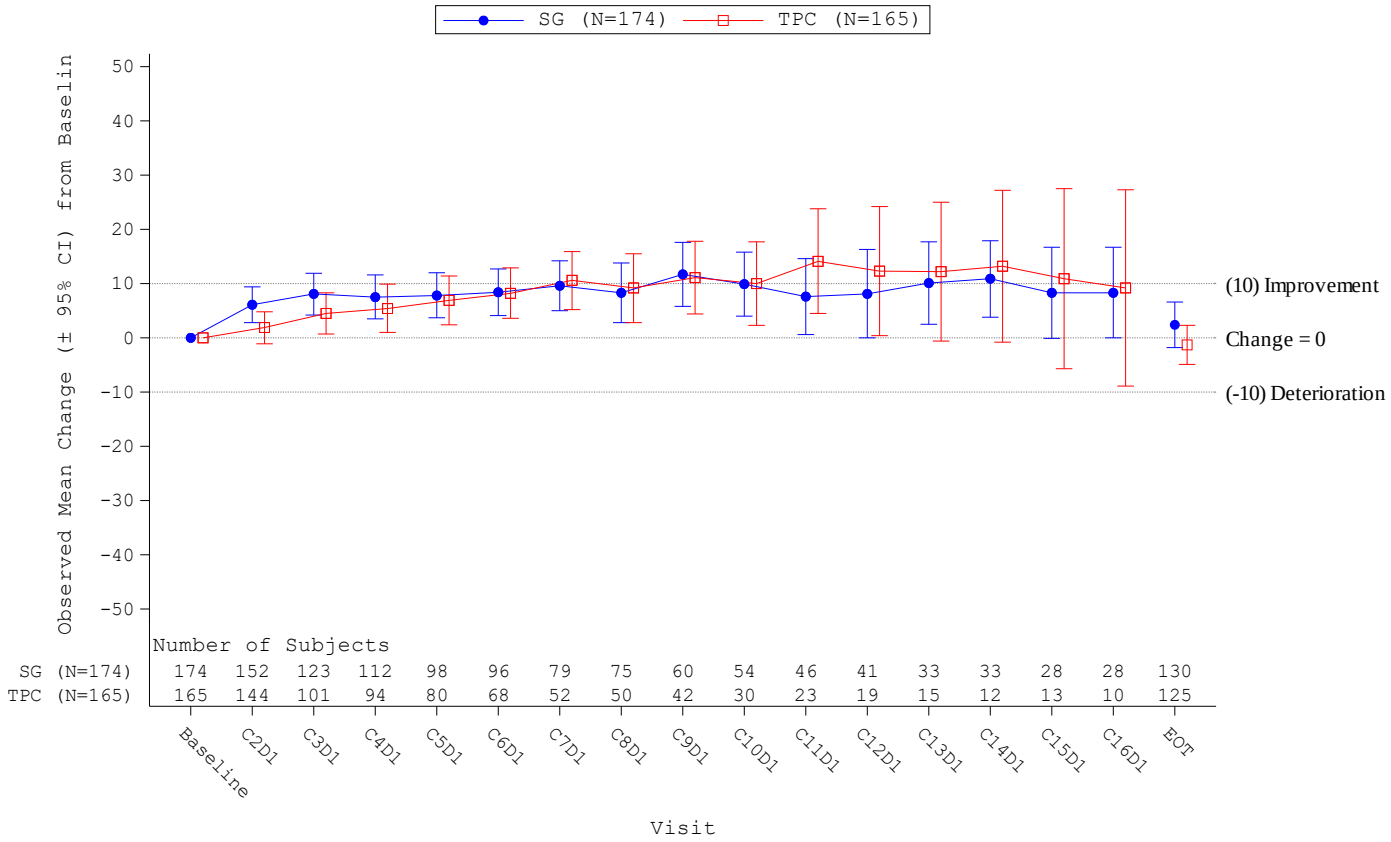
Figure 15.15.1.1.4
Observed Mean Change from Baseline in EORTC QLQ-C30 Emotional Functioning by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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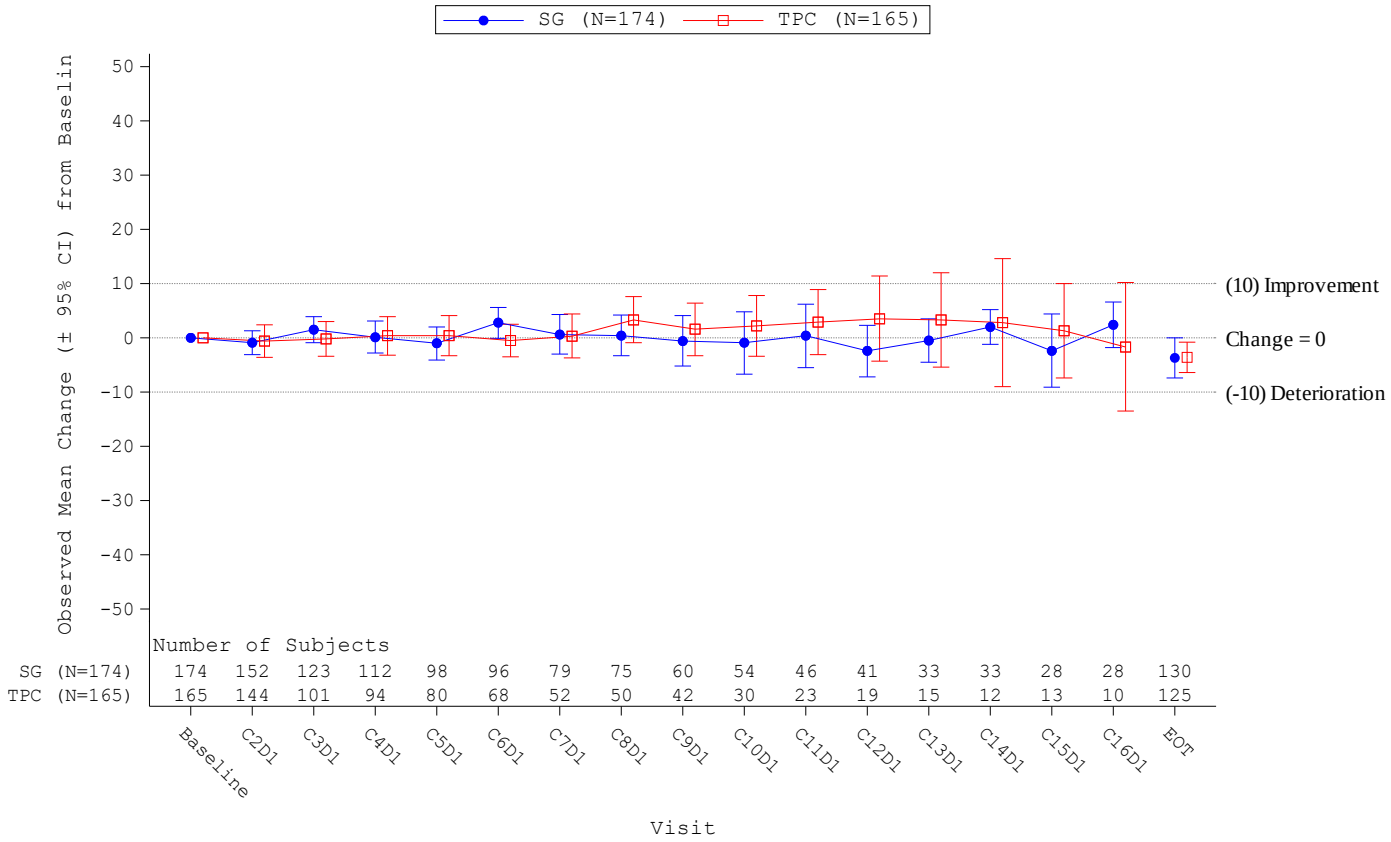
Figure 15.15.1.1.5
Observed Mean Change from Baseline in EORTC QLQ-C30 Cognitive Functioning by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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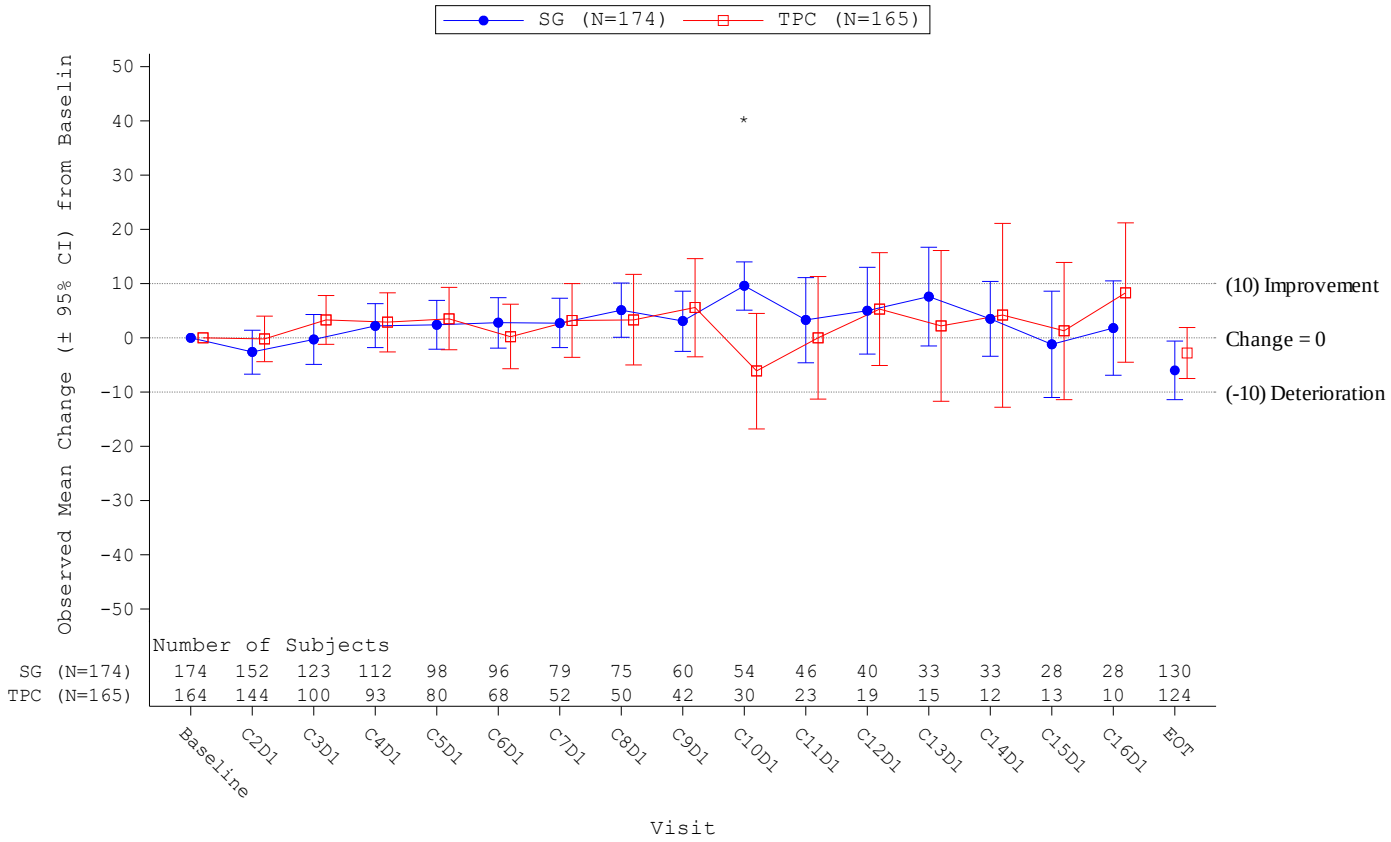
Figure 15.15.1.1.6
Observed Mean Change from Baseline in EORTC QLQ-C30 Social Functioning by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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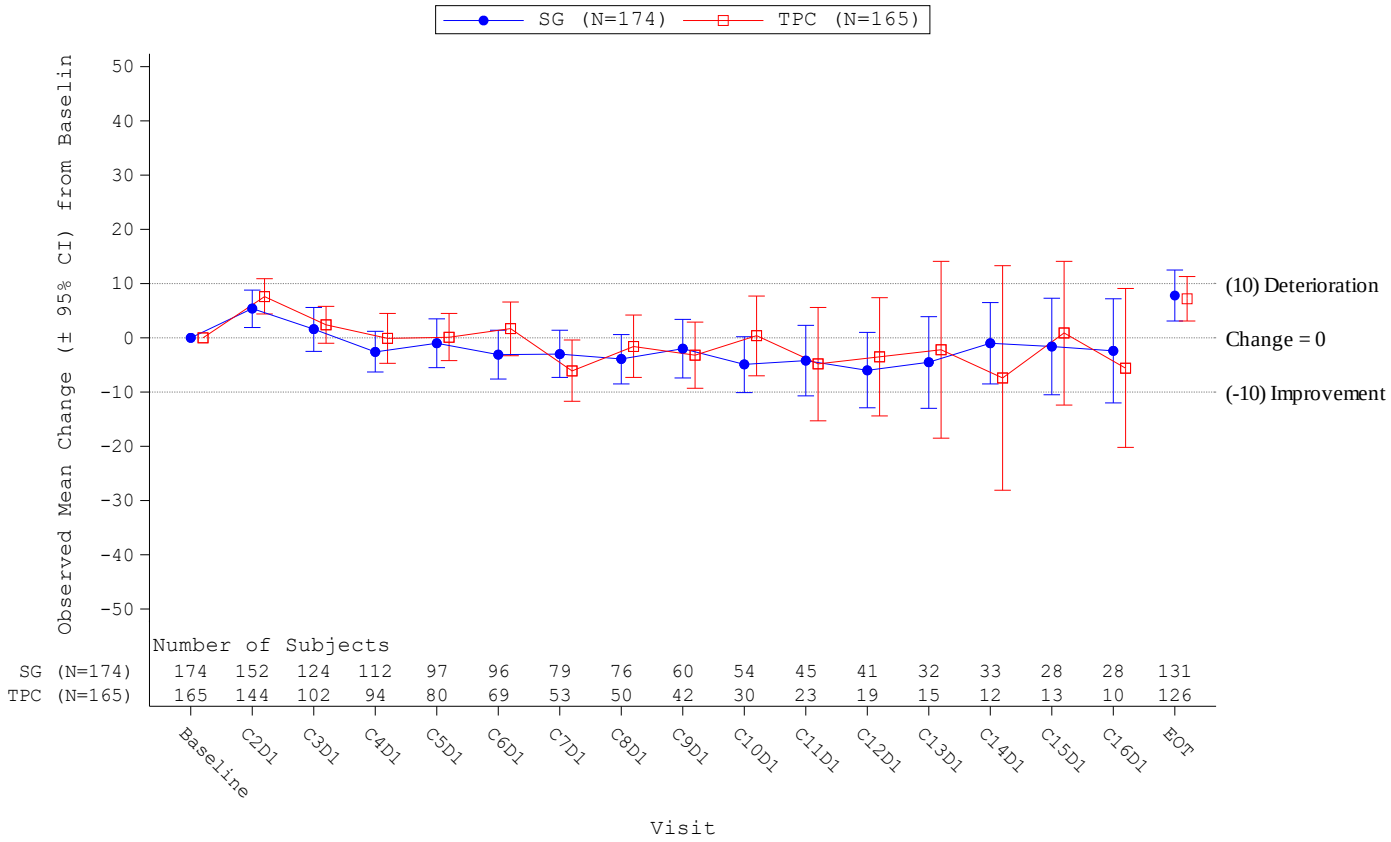
Figure 15.15.1.1.7
Observed Mean Change from Baseline in EORTC QLQ-C30 Fatigue by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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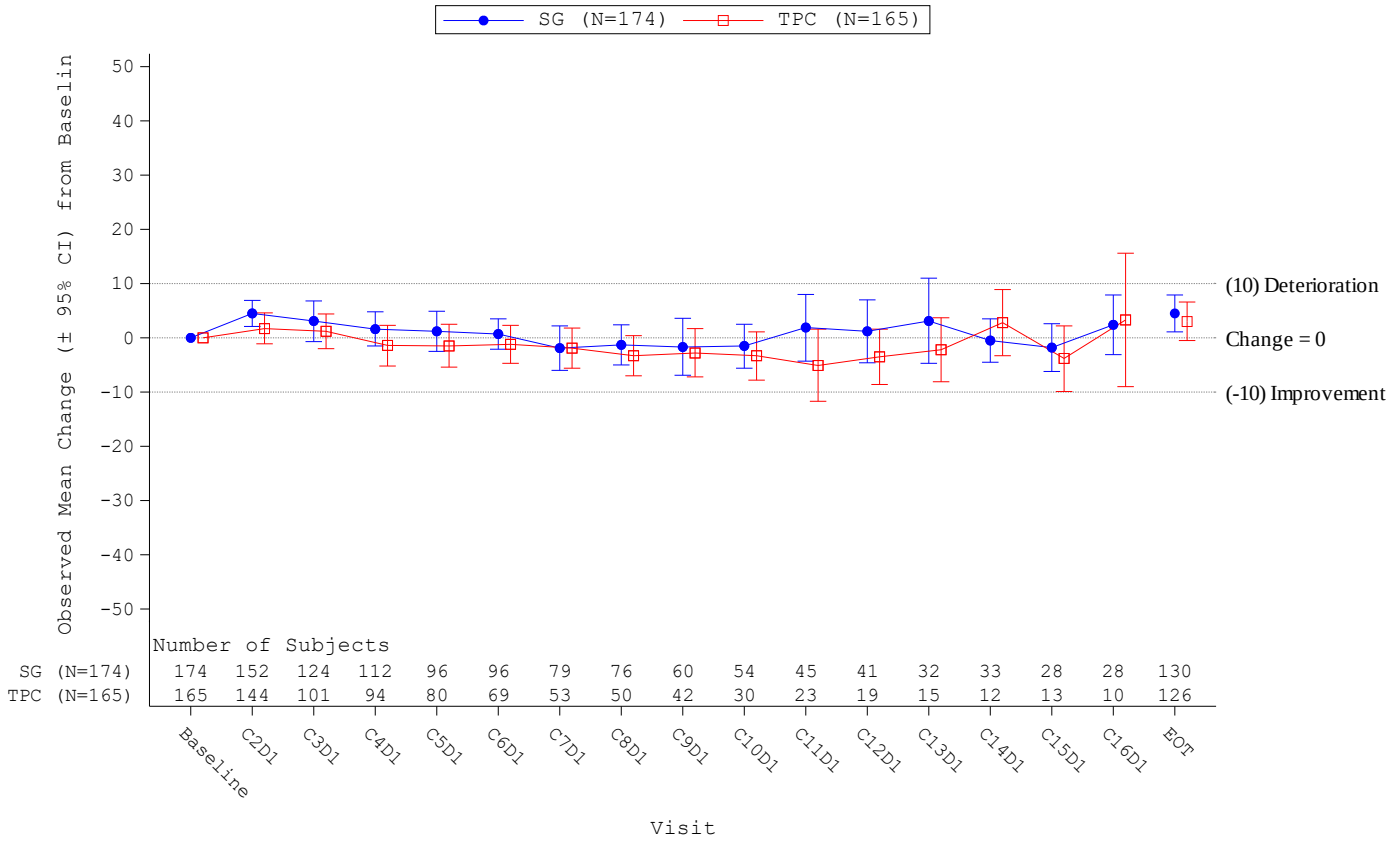
Figure 15.15.1.1.8
Observed Mean Change from Baseline in EORTC QLQ-C30 Nausea and Vomiting by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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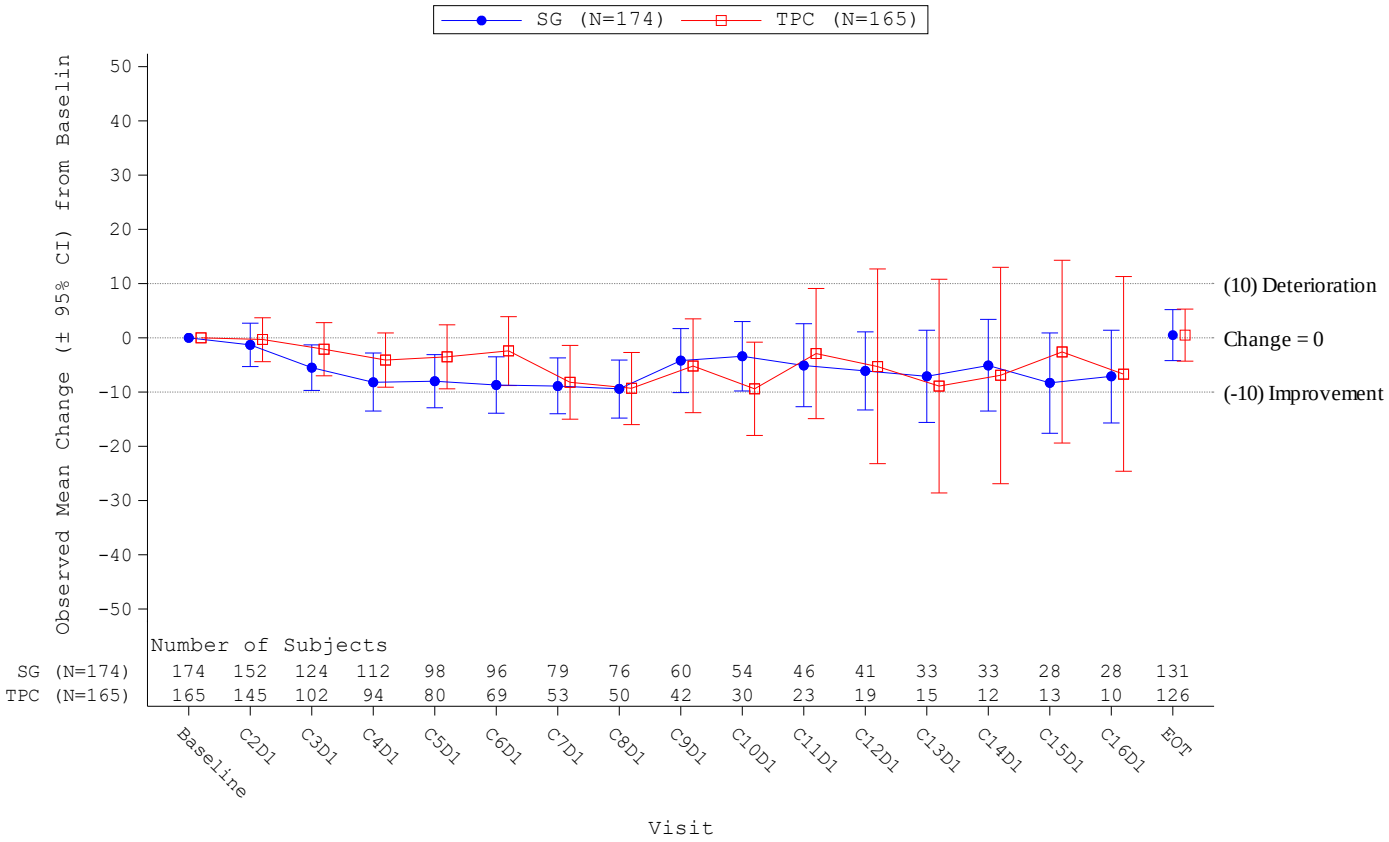
Figure 15.15.1.1.9
Observed Mean Change from Baseline in EORTC QLQ-C30 Pain by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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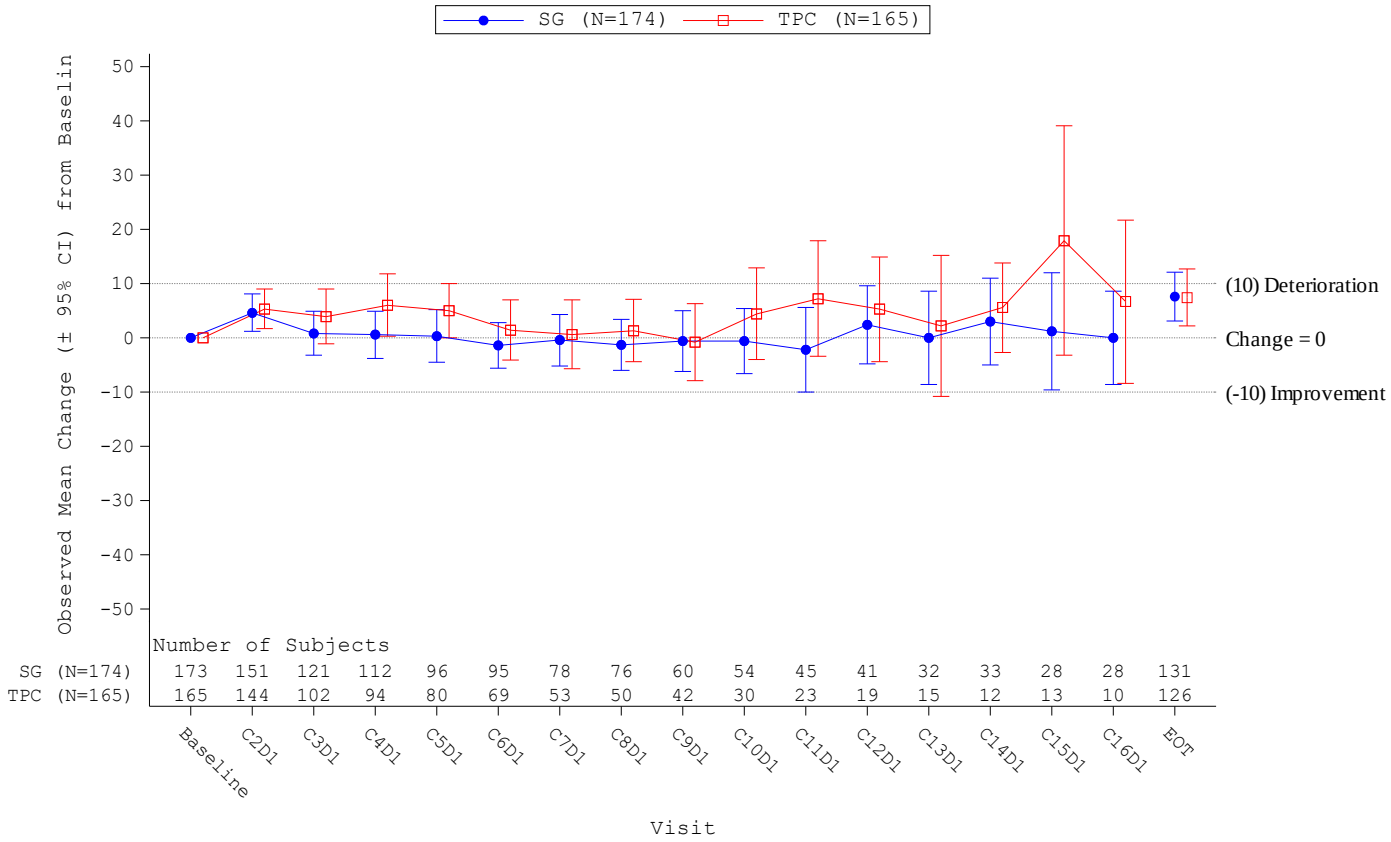
Figure 15.15.1.1.10
Observed Mean Change from Baseline in EORTC QLQ-C30 Dyspnea by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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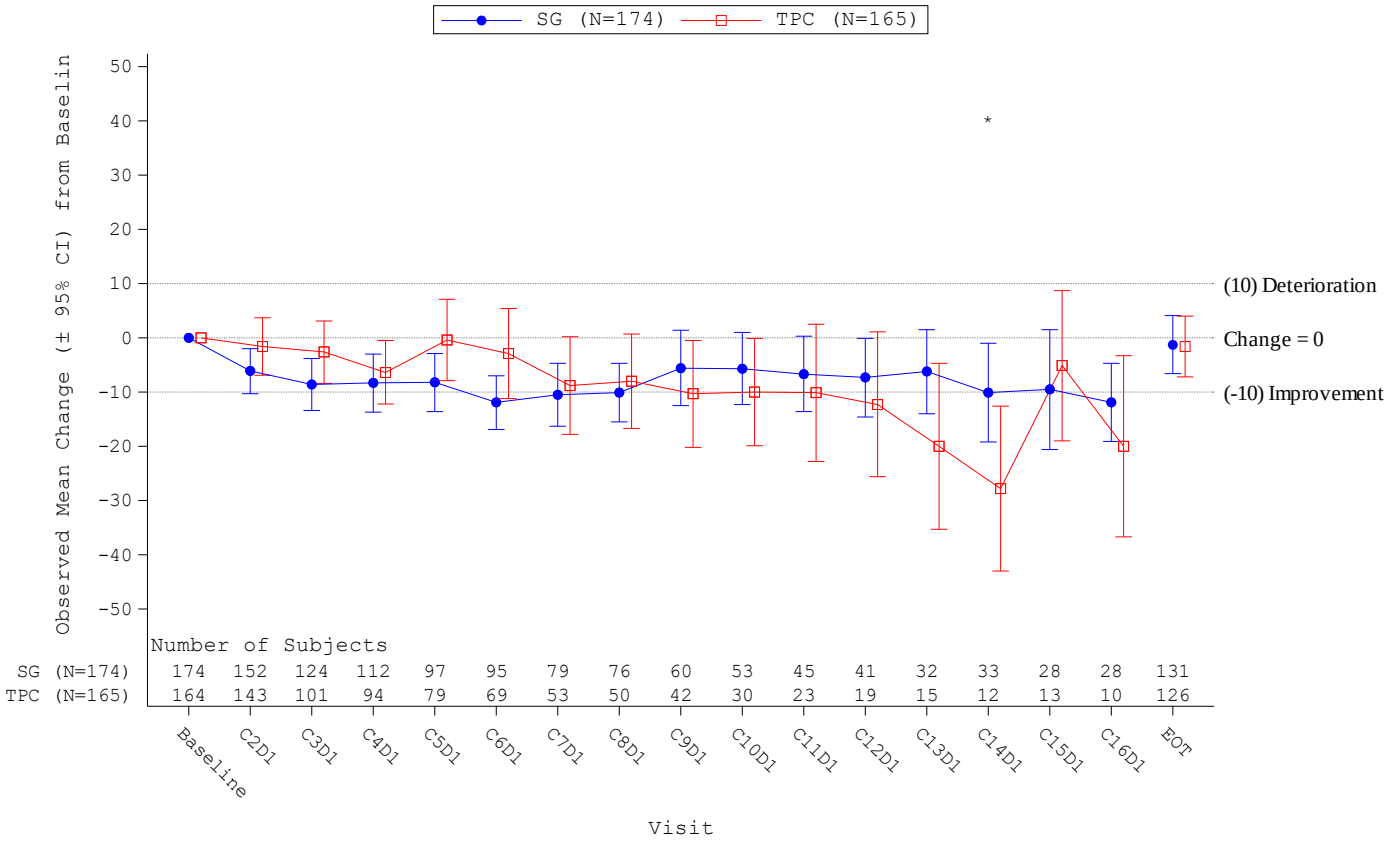
Figure 15.15.1.1.11
Observed Mean Change from Baseline in EORTC QLQ-C30 Insomnia by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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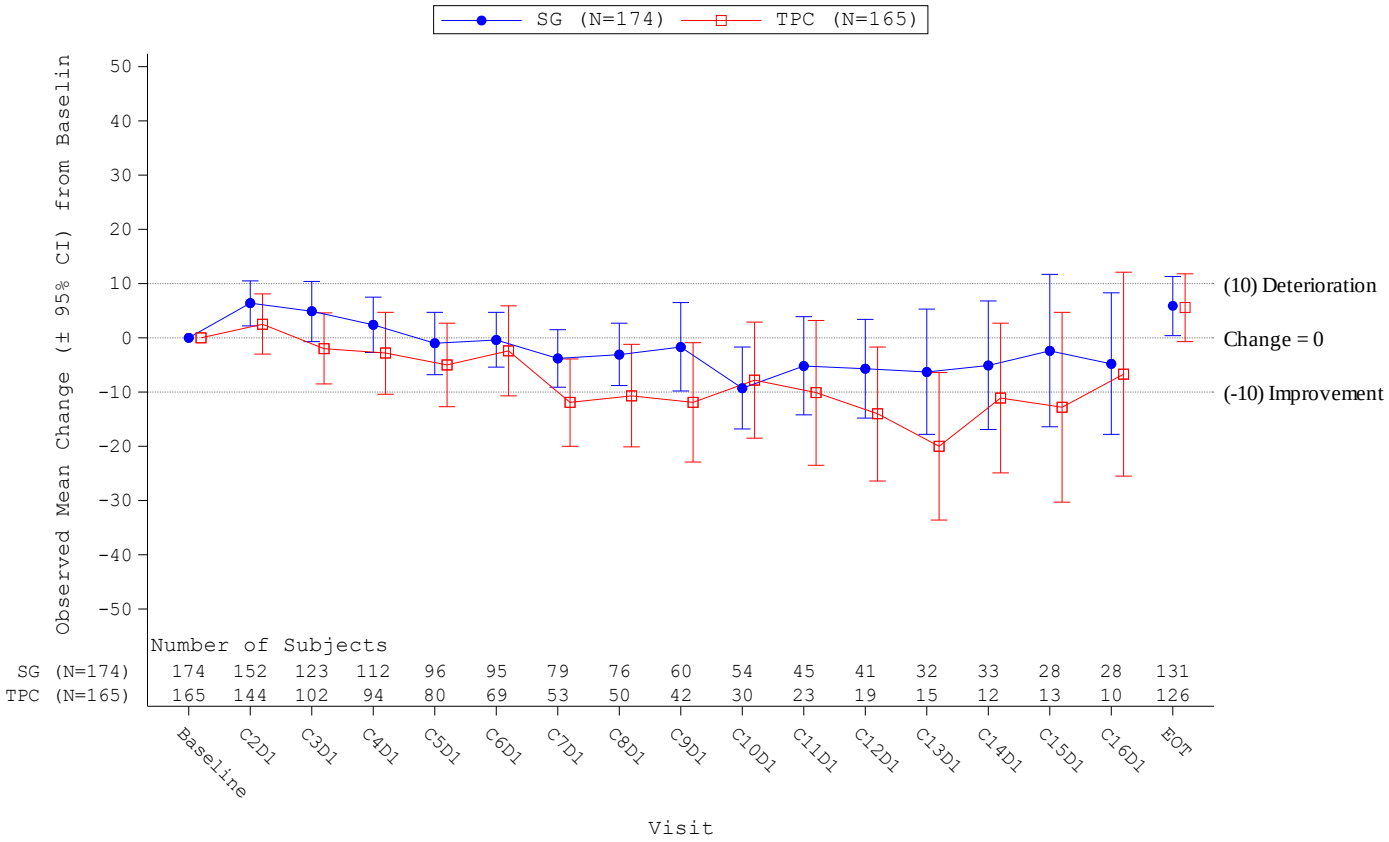
Figure 15.15.1.1.12
Observed Mean Change from Baseline in EORTC QLQ-C30 Appetite Loss by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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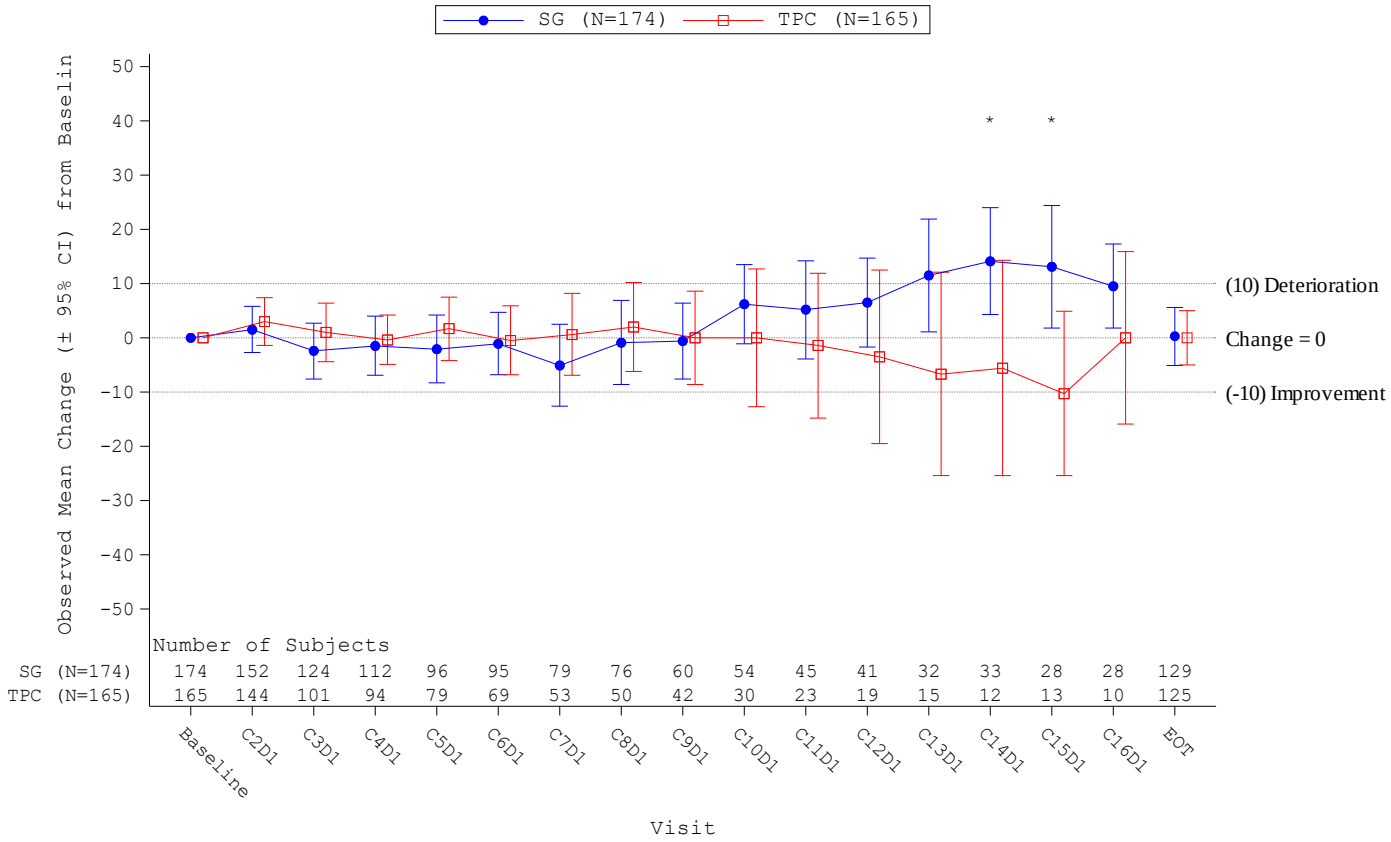
Figure 15.15.1.1.13
Observed Mean Change from Baseline in EORTC QLQ-C30 Constipation by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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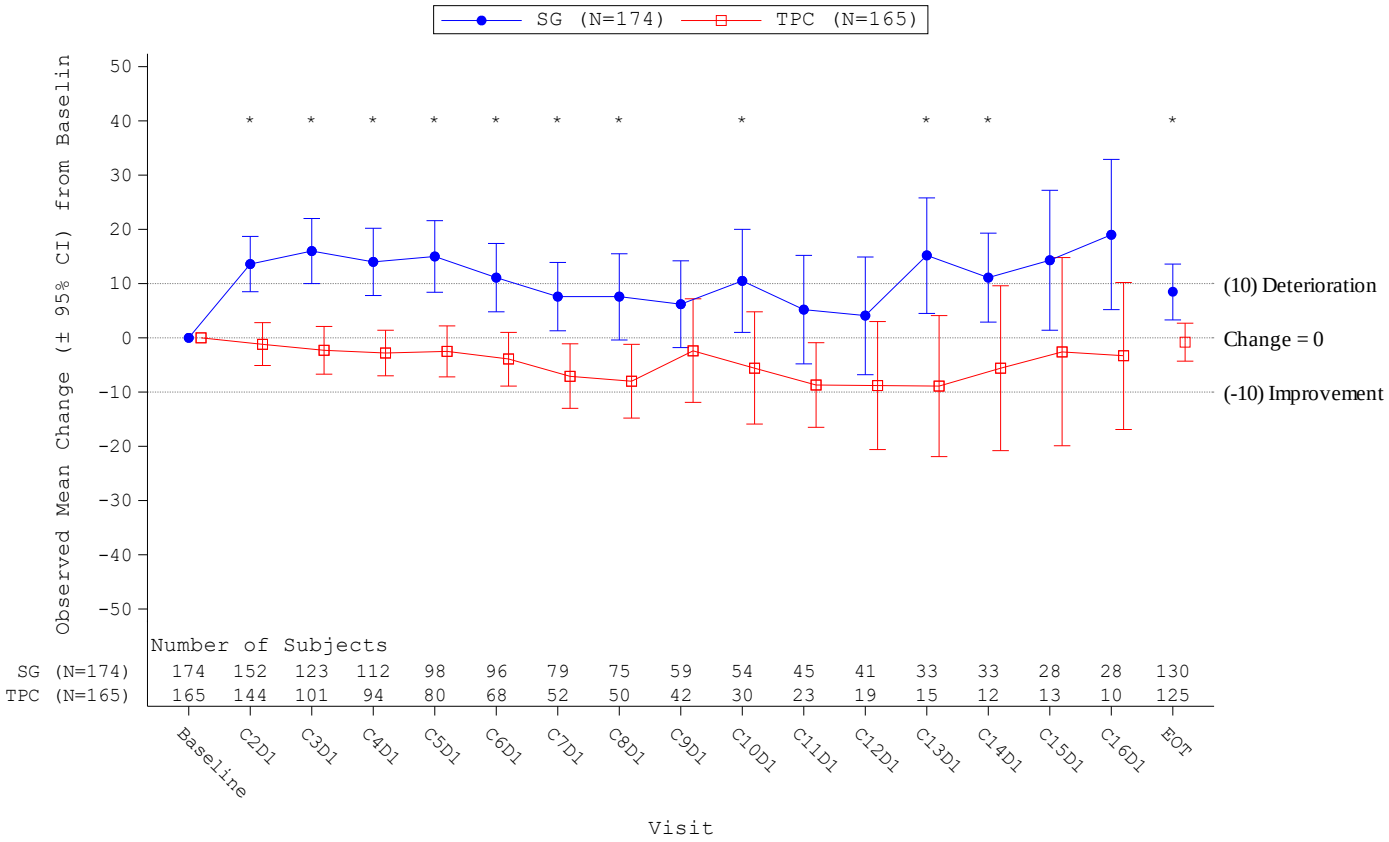
Figure 15.15.1.1.14
Observed Mean Change from Baseline in EORTC QLQ-C30 Diarrhea by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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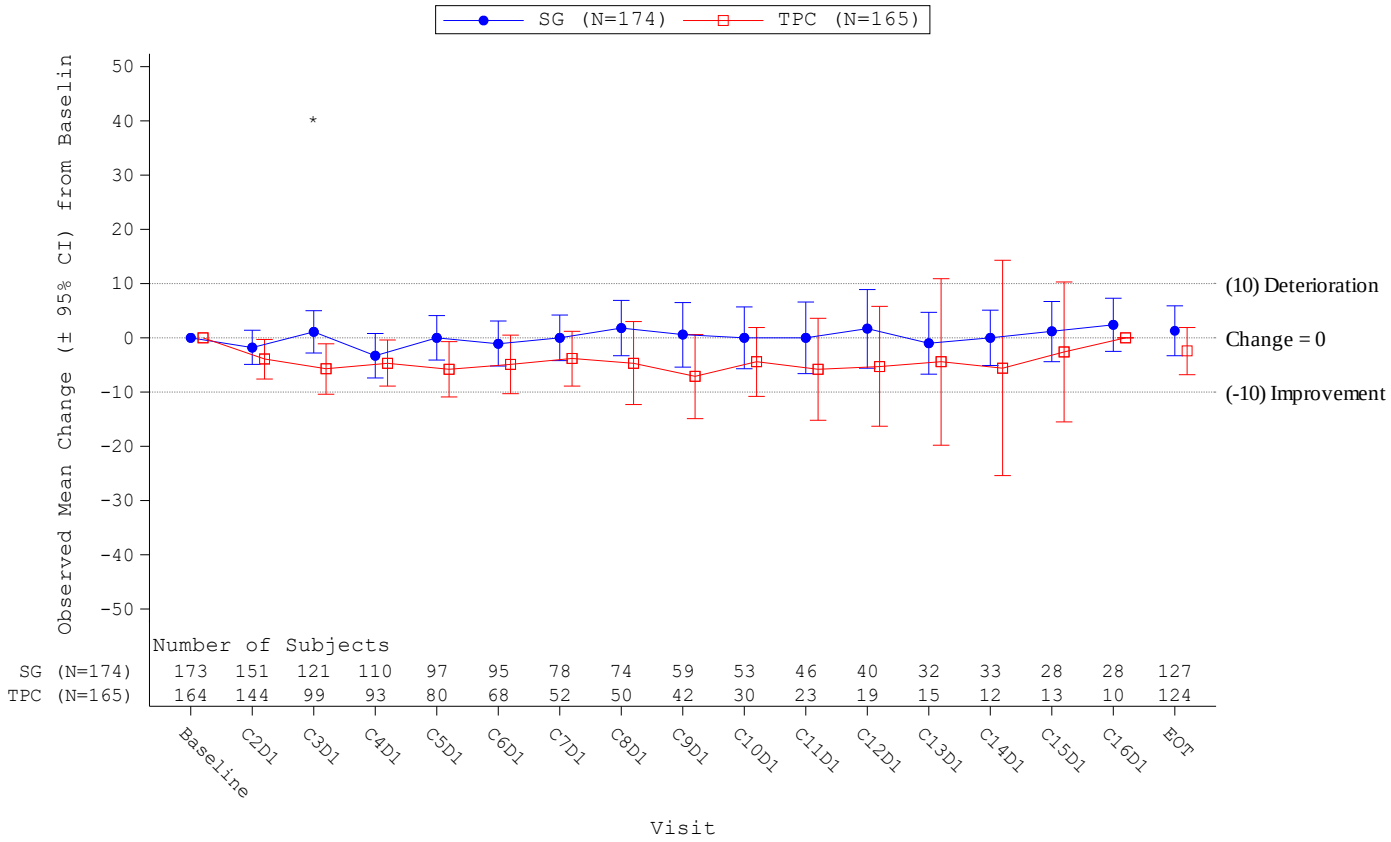
Figure 15.15.1.1.15
Observed Mean Change from Baseline in EORTC QLQ-C30 Financial Difficulties by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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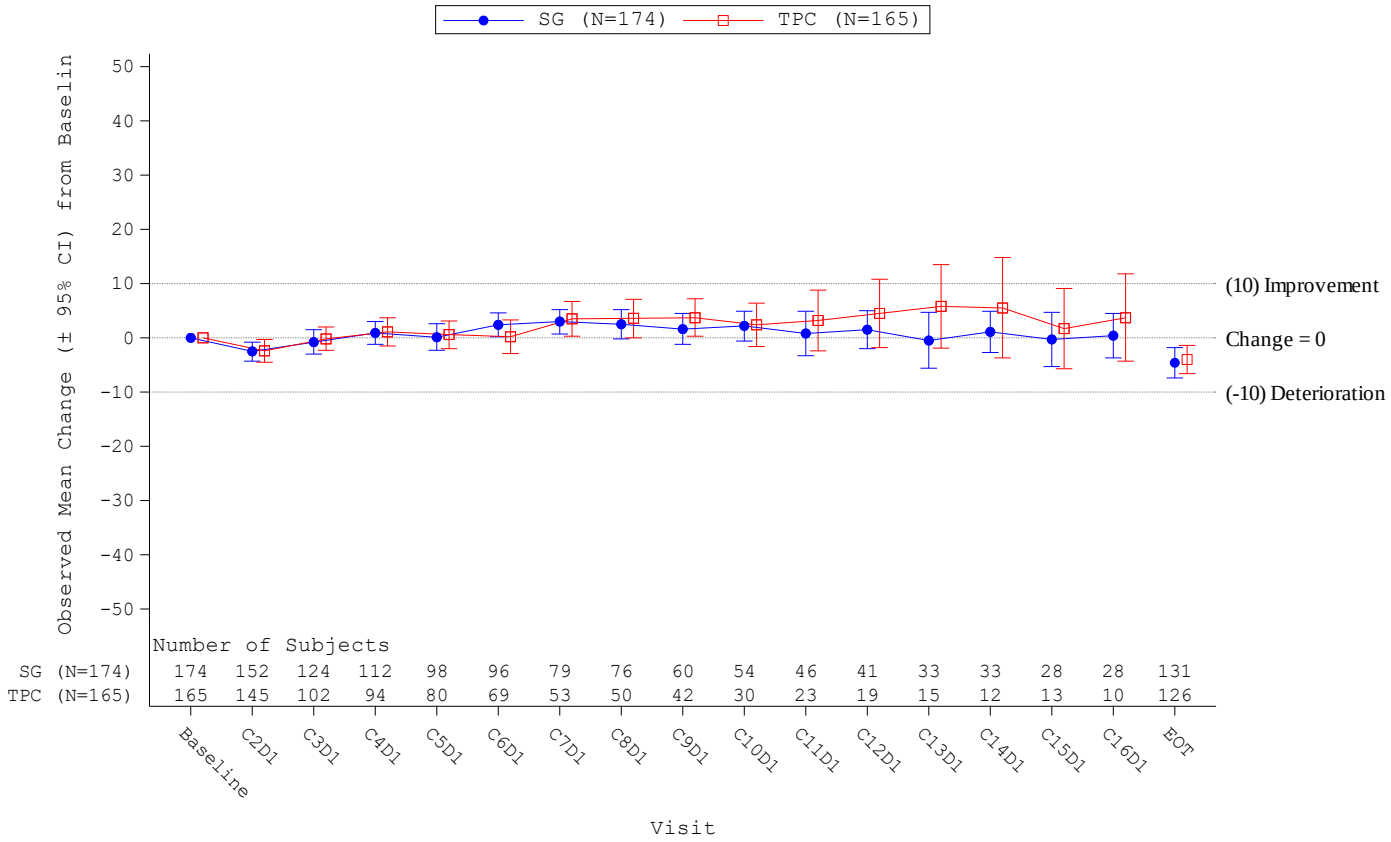
Figure 15.15.1.1.16
Observed Mean Change from Baseline in EORTC QLQ-C30 Summary Score by Visit and Treatment Group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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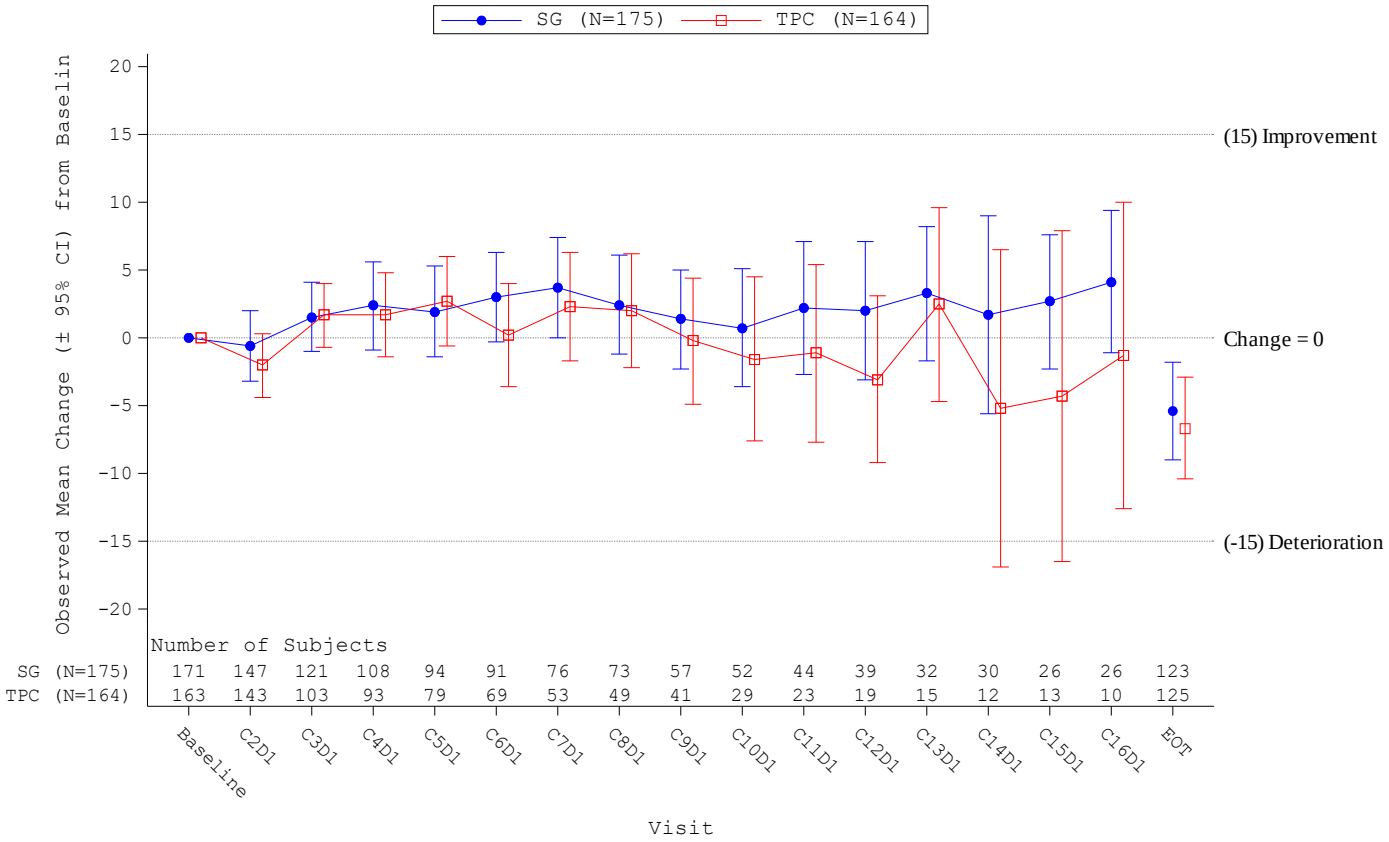
Figure 15.15.1.2
Observed Mean Change from Baseline in EQ-5D VAS by Visit and Treatment Group
EQ-5D-5L Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. Changes from baseline are used as the dependent variable. Results are presented up to the visit with n ≥10 for each treatment arm. EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

* Indicates a statistically significant difference in observed mean change from baseline between treatment arms (SG vs. TPC) at a specific post-baseline assessment visit based on a 2-sample 2-sided t-test.

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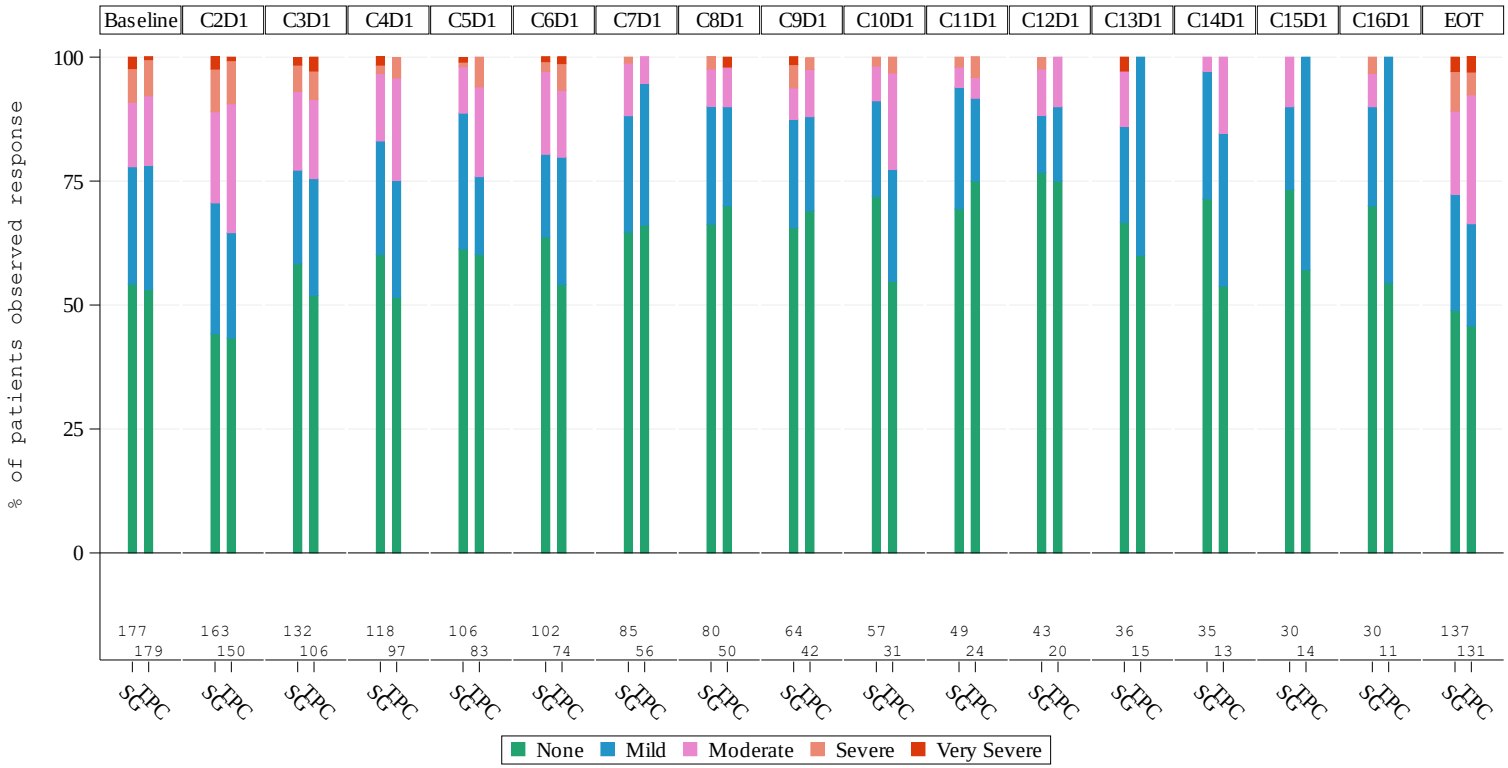
Figure 15.15.2.1
Distribution of Responses to the PRO-CTCAE Decreased Appetite Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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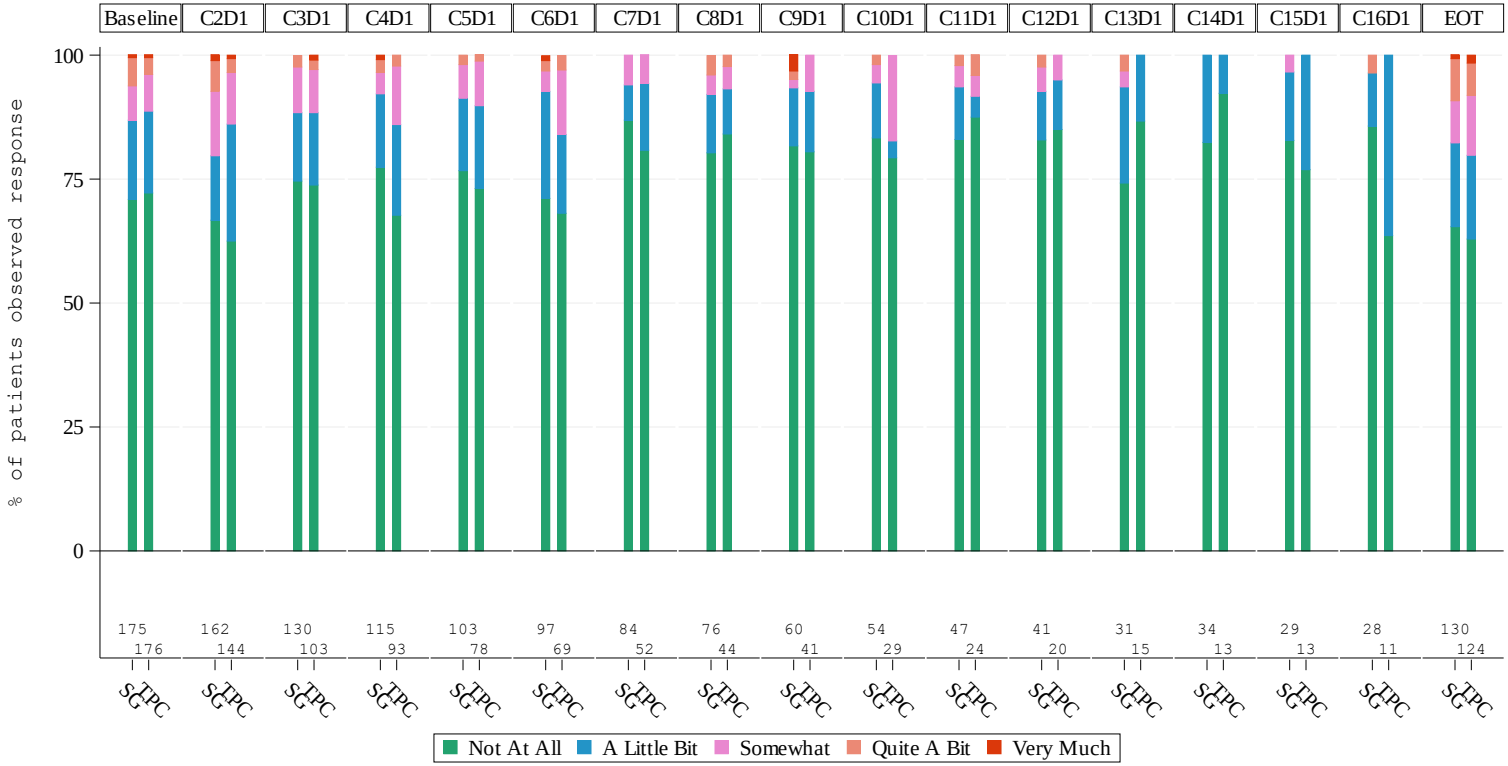
Figure 15.15.2.2
Distribution of Responses to the PRO-CTCAE Decreased Appetite Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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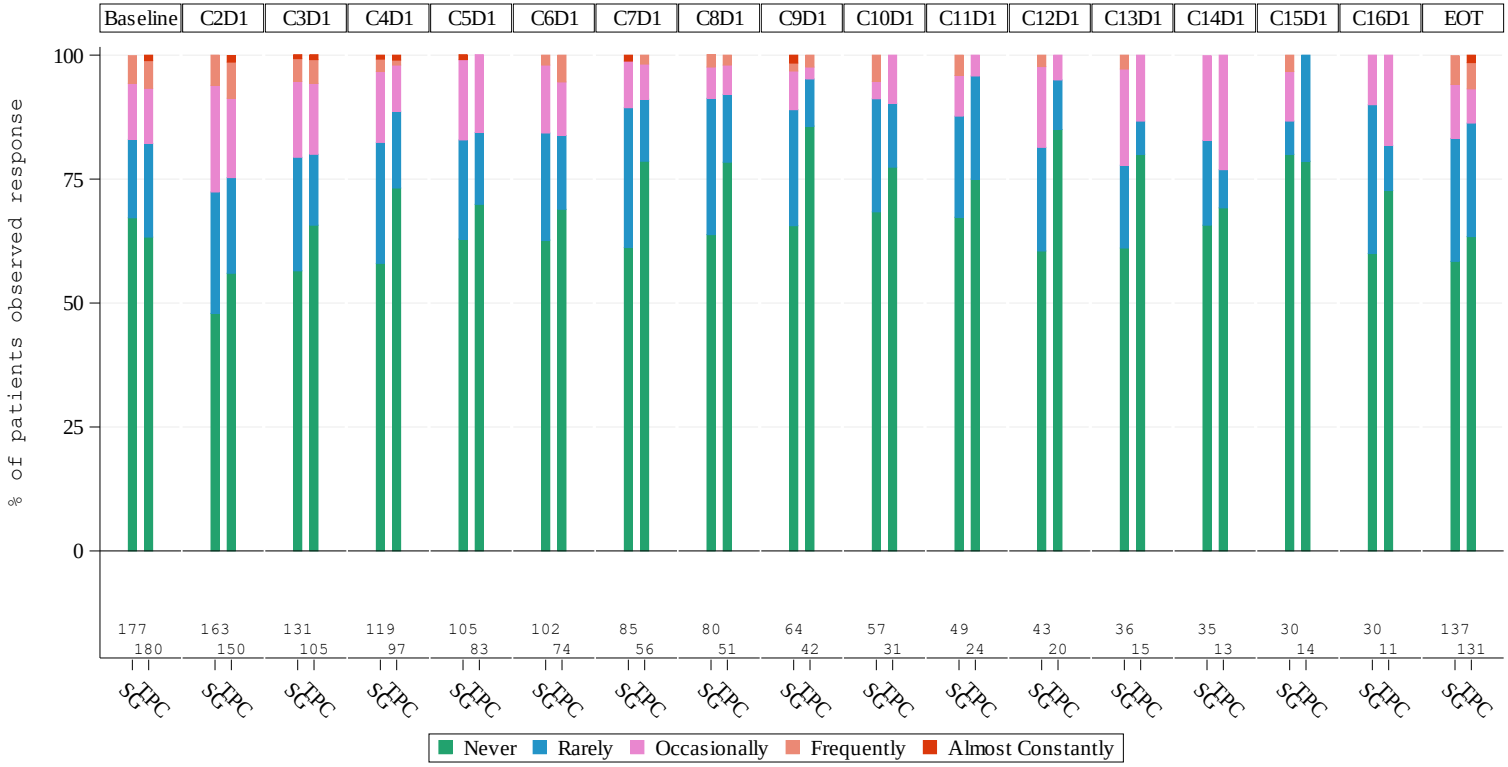
Figure 15.15.2.3
Distribution of Responses to the PRO-CTCAE Nausea Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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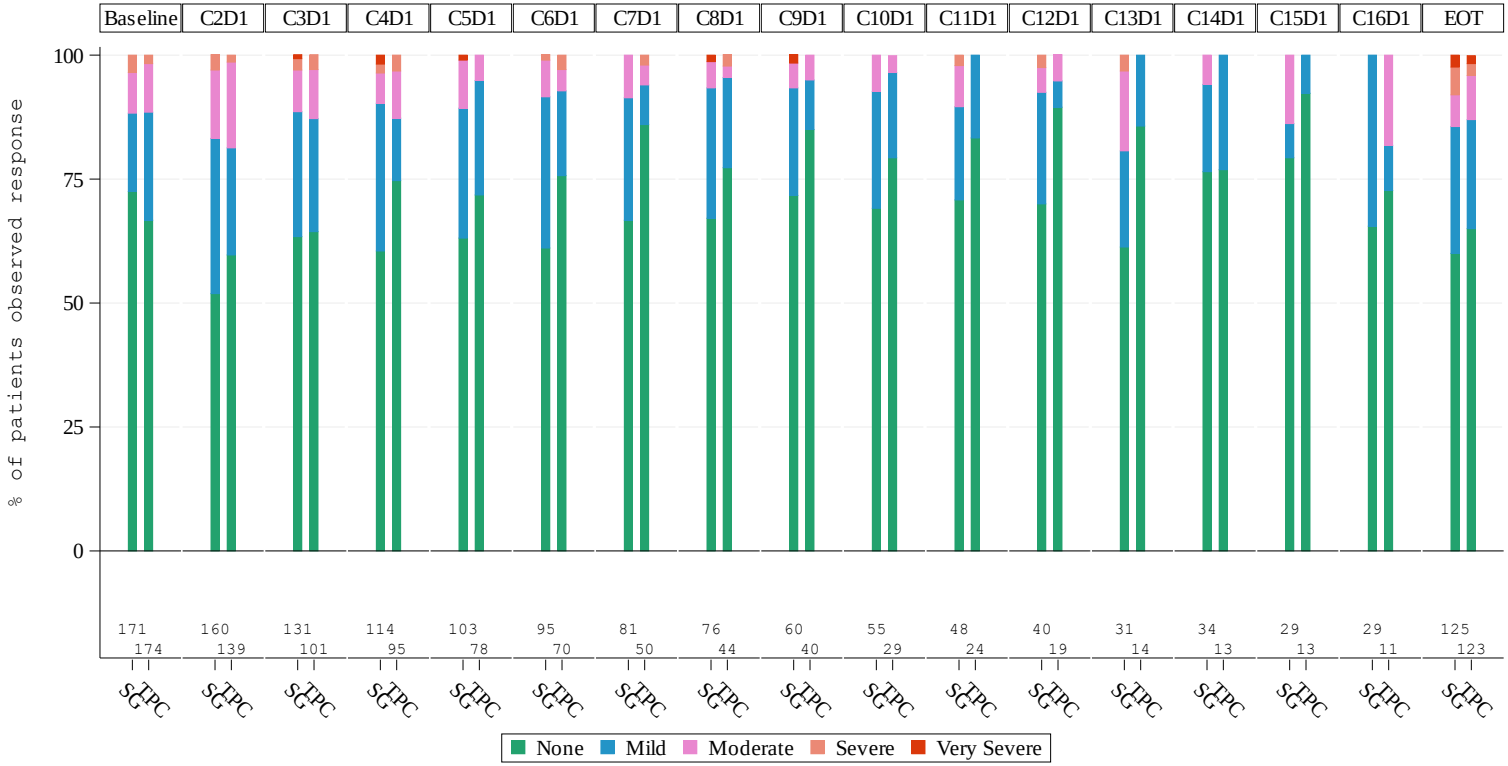
Figure 15.15.2.4
Distribution of Responses to the PRO-CTCAE Nausea Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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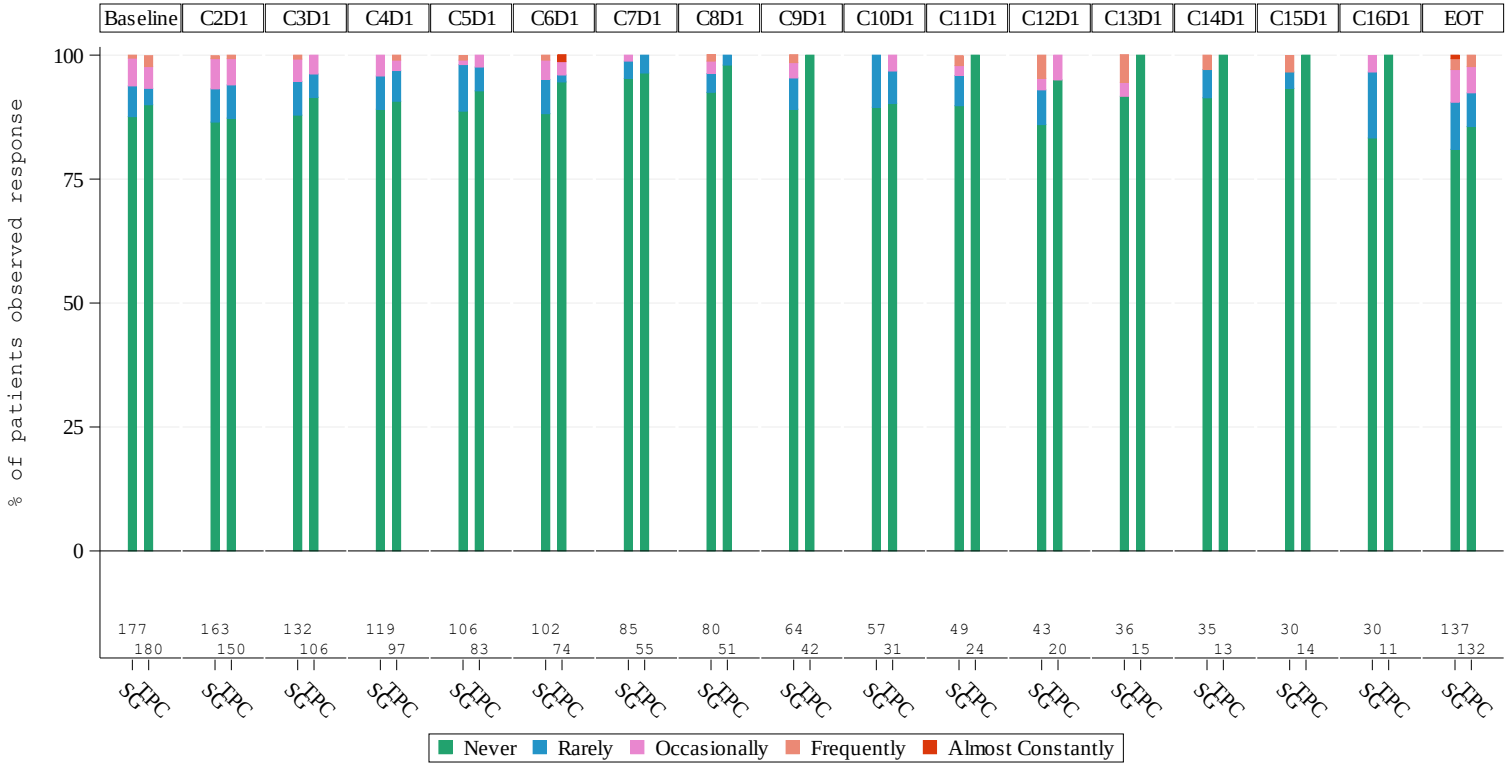
Figure 15.15.2.5
Distribution of Responses to the PRO-CTCAE Vomiting Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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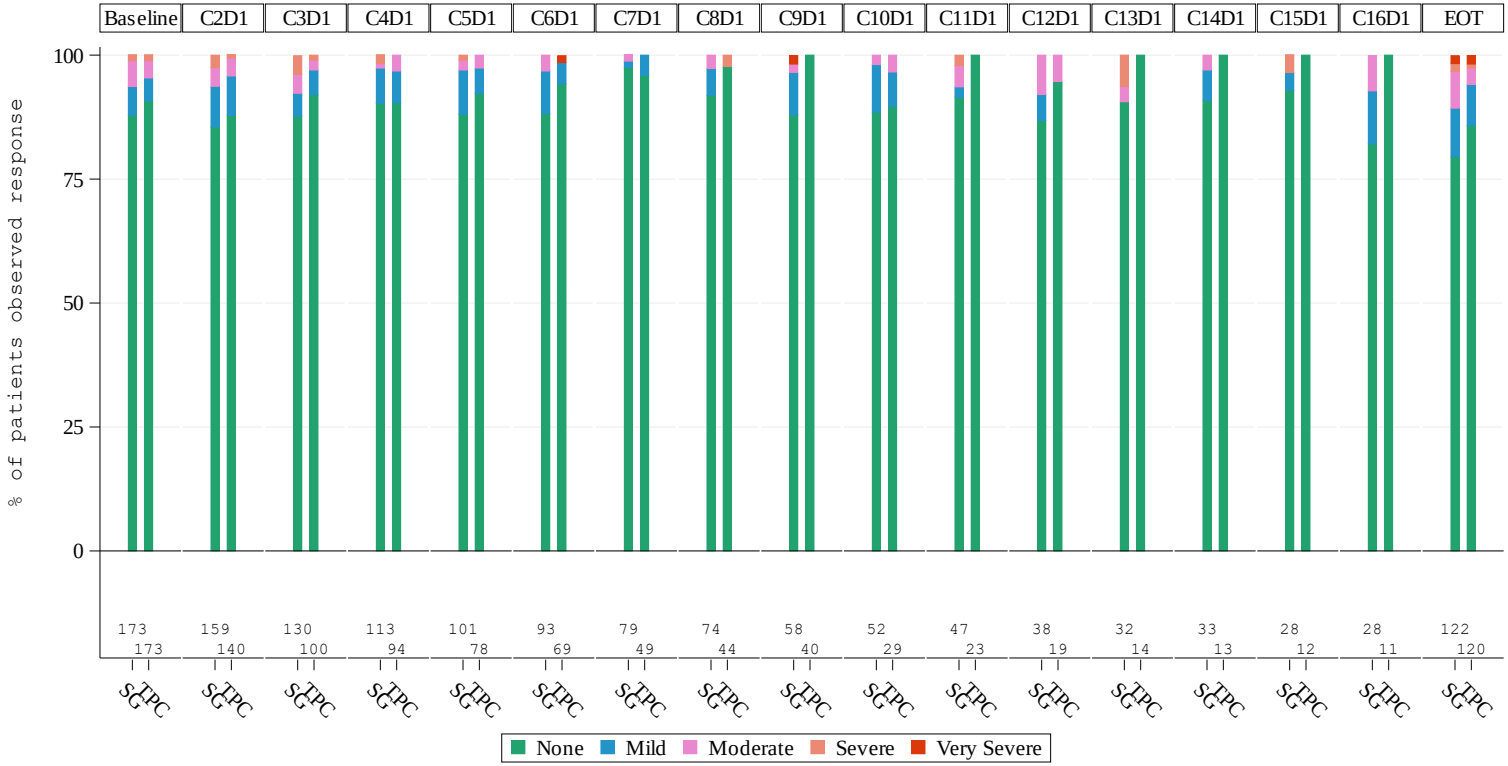
Figure 15.15.2.6
Distribution of Responses to the PRO-CTCAE Vomiting Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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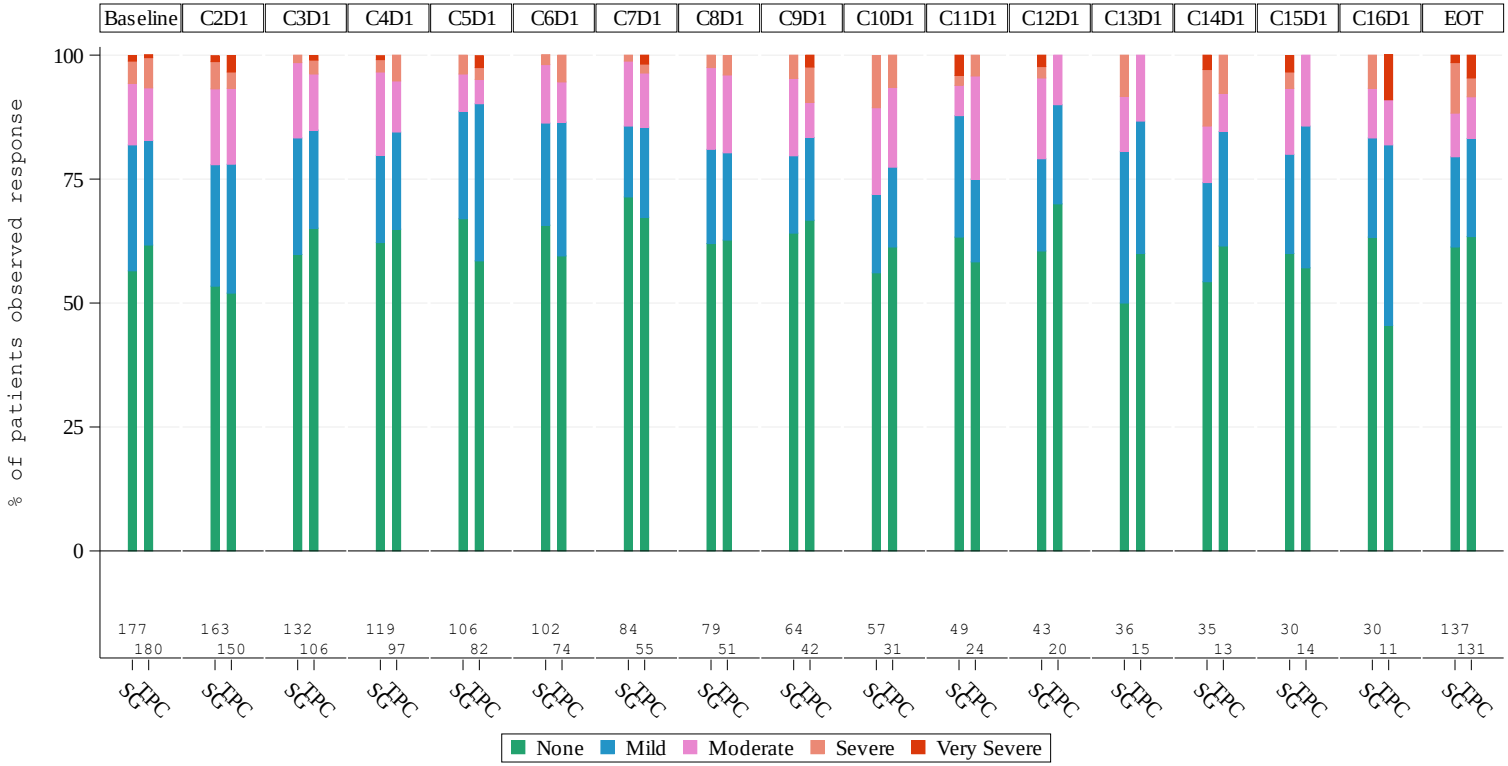
Figure 15.15.2.7
Distribution of Responses to the PRO-CTCAE Constipation Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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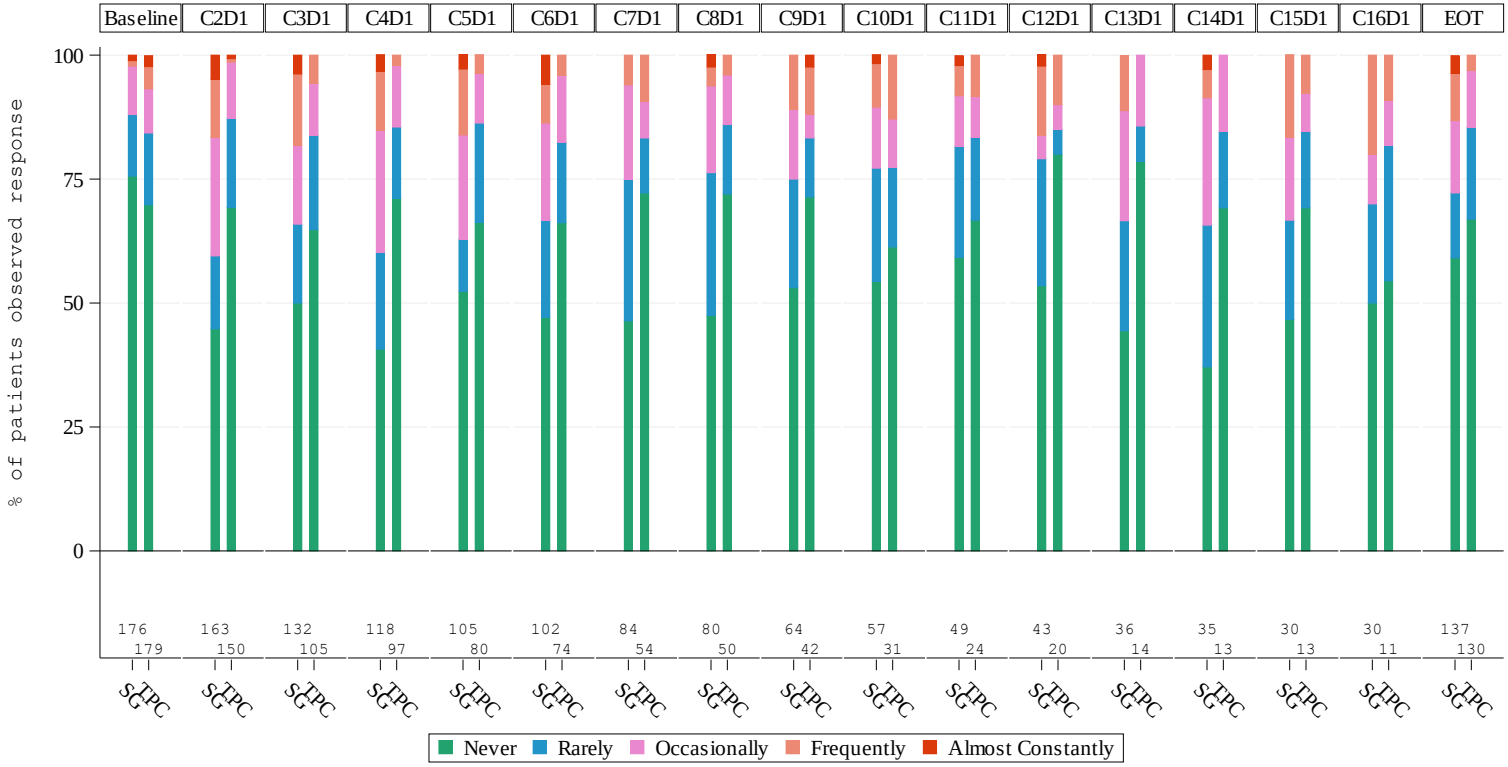
Figure 15.15.2.8
Distribution of Responses to the PRO-CTCAE Diarrhea Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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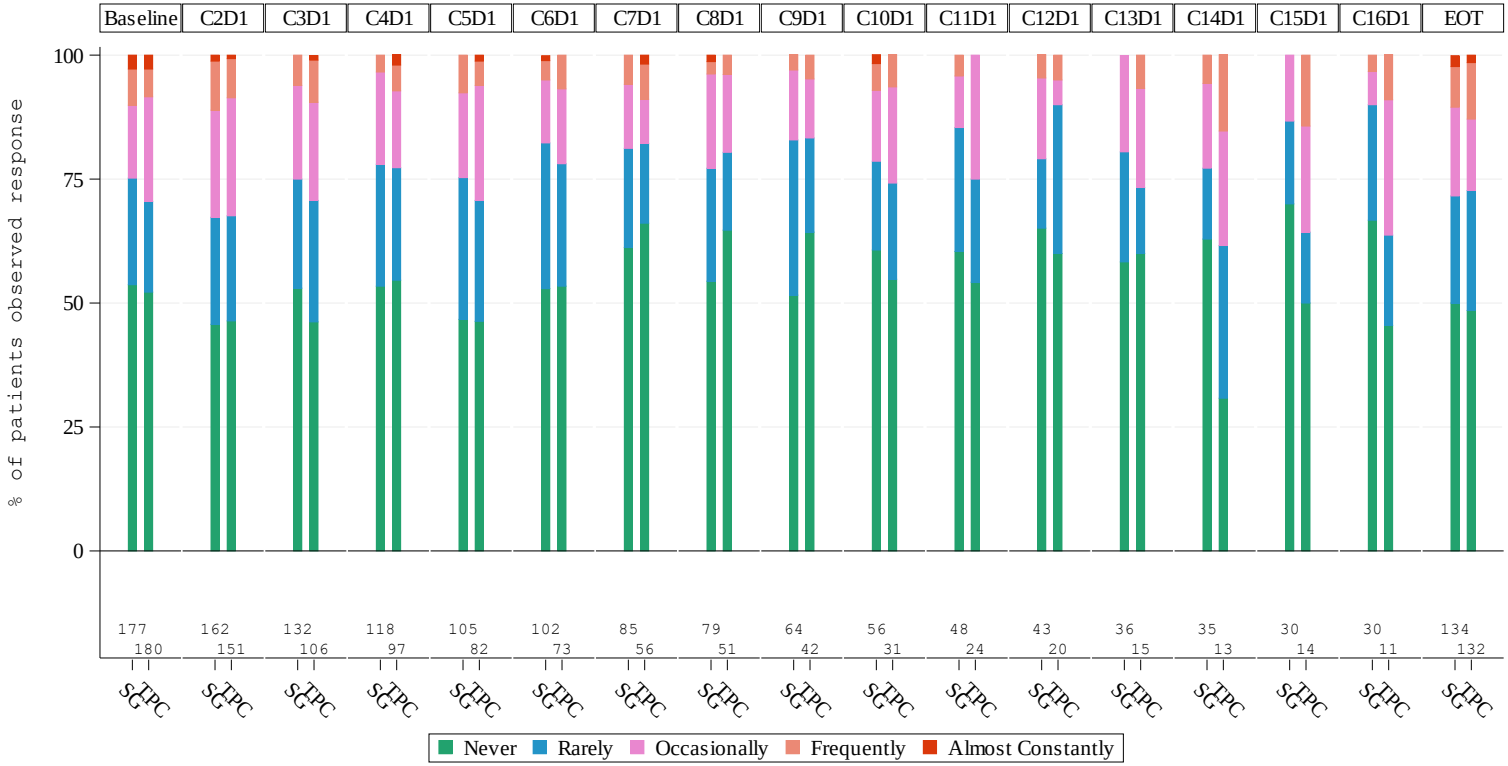
Figure 15.15.2.9
Distribution of Responses to the PRO-CTCAE Abdominal Pain Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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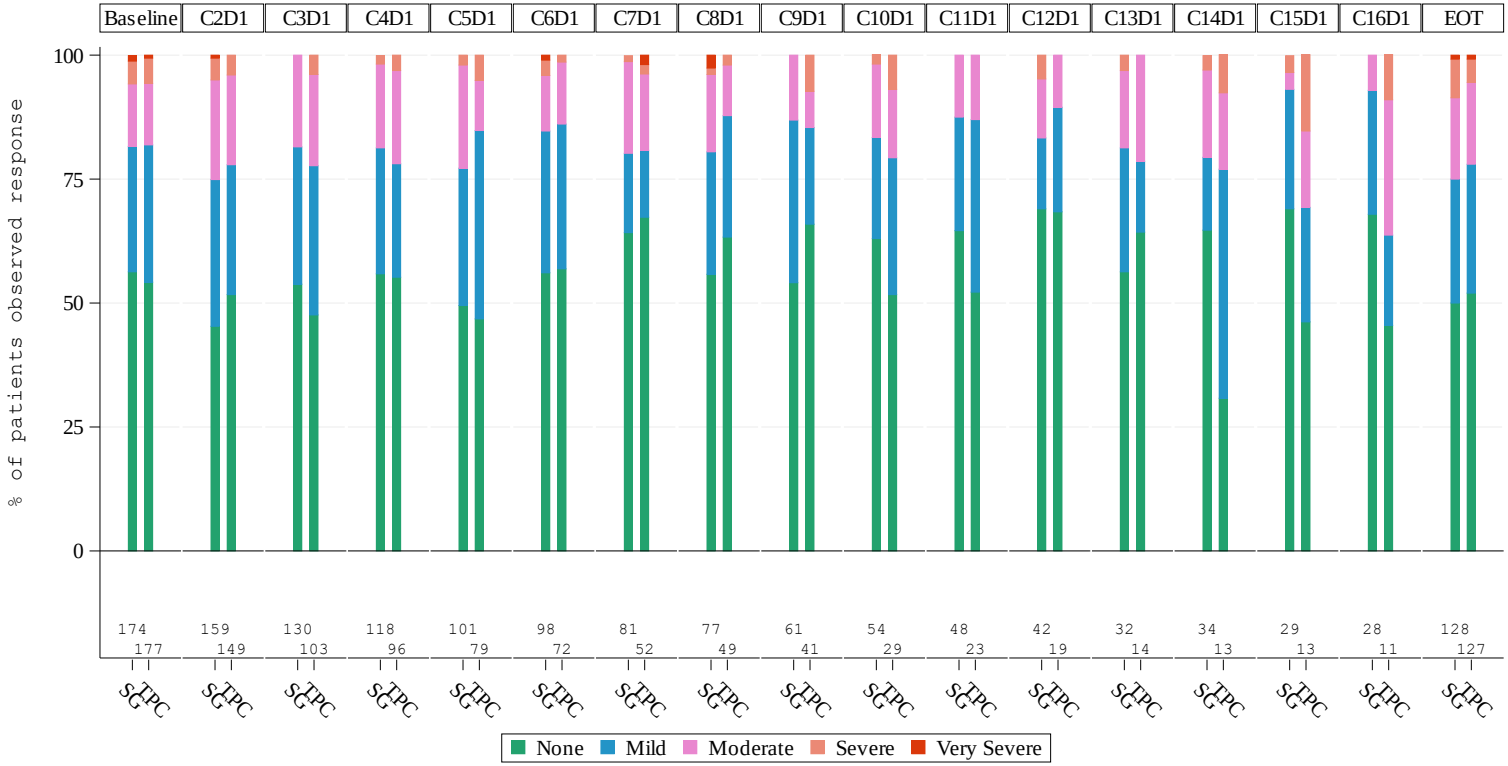
Figure 15.15.2.10
Distribution of Responses to the PRO-CTCAE Abdominal Pain Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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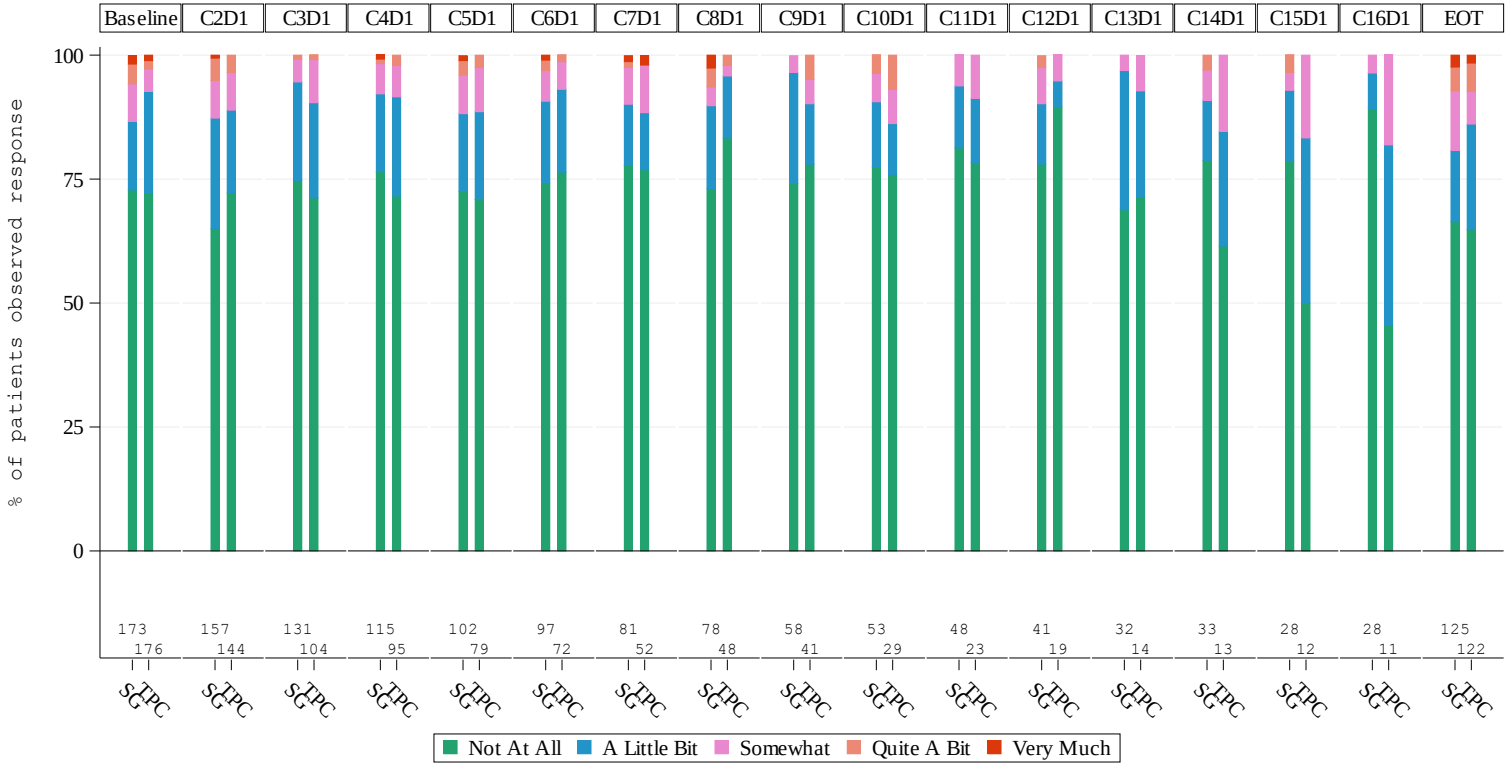
Figure 15.15.2.11
Distribution of Responses to the PRO-CTCAE Abdominal Pain Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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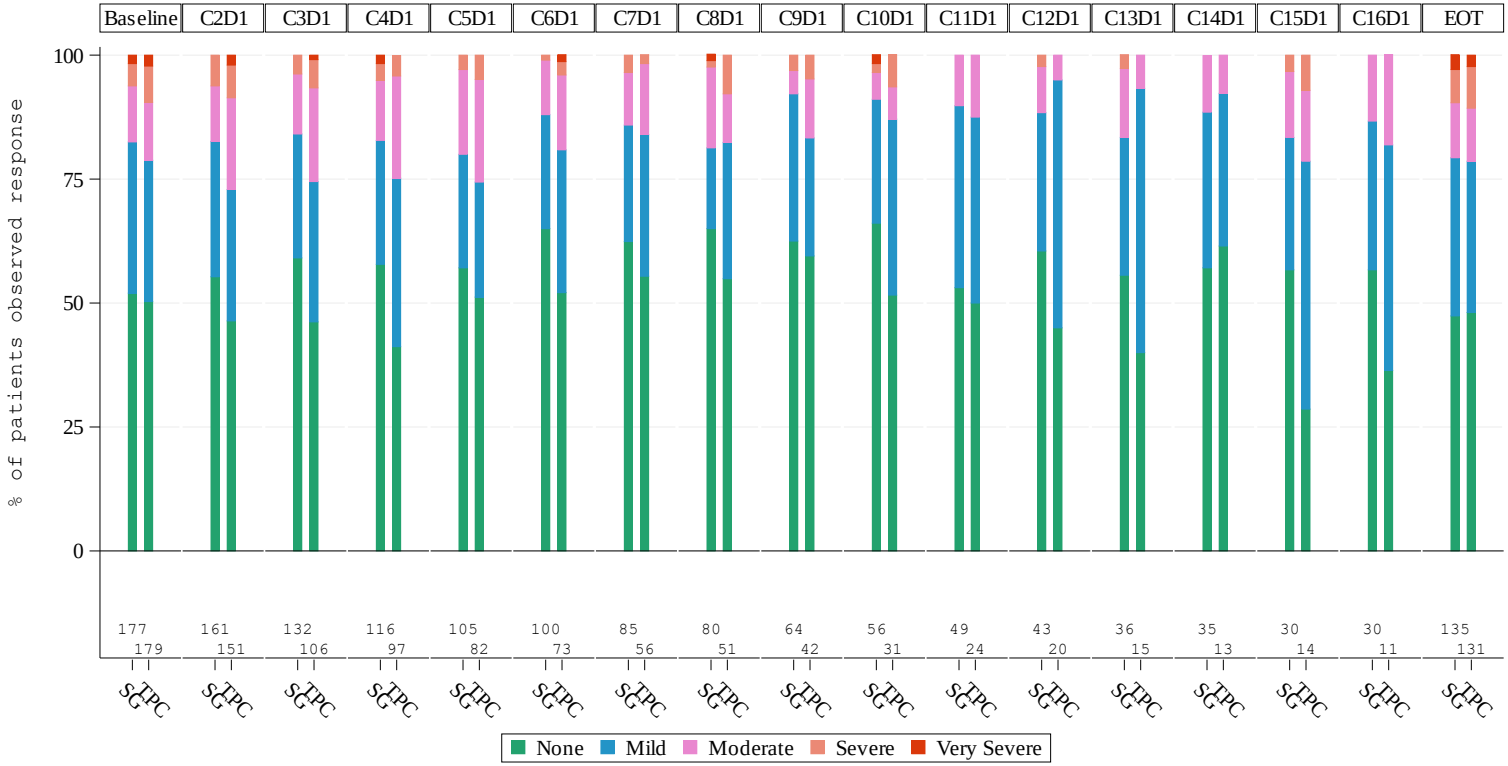
Figure 15.15.2.12
Distribution of Responses to the PRO-CTCAE Shortness of Breath Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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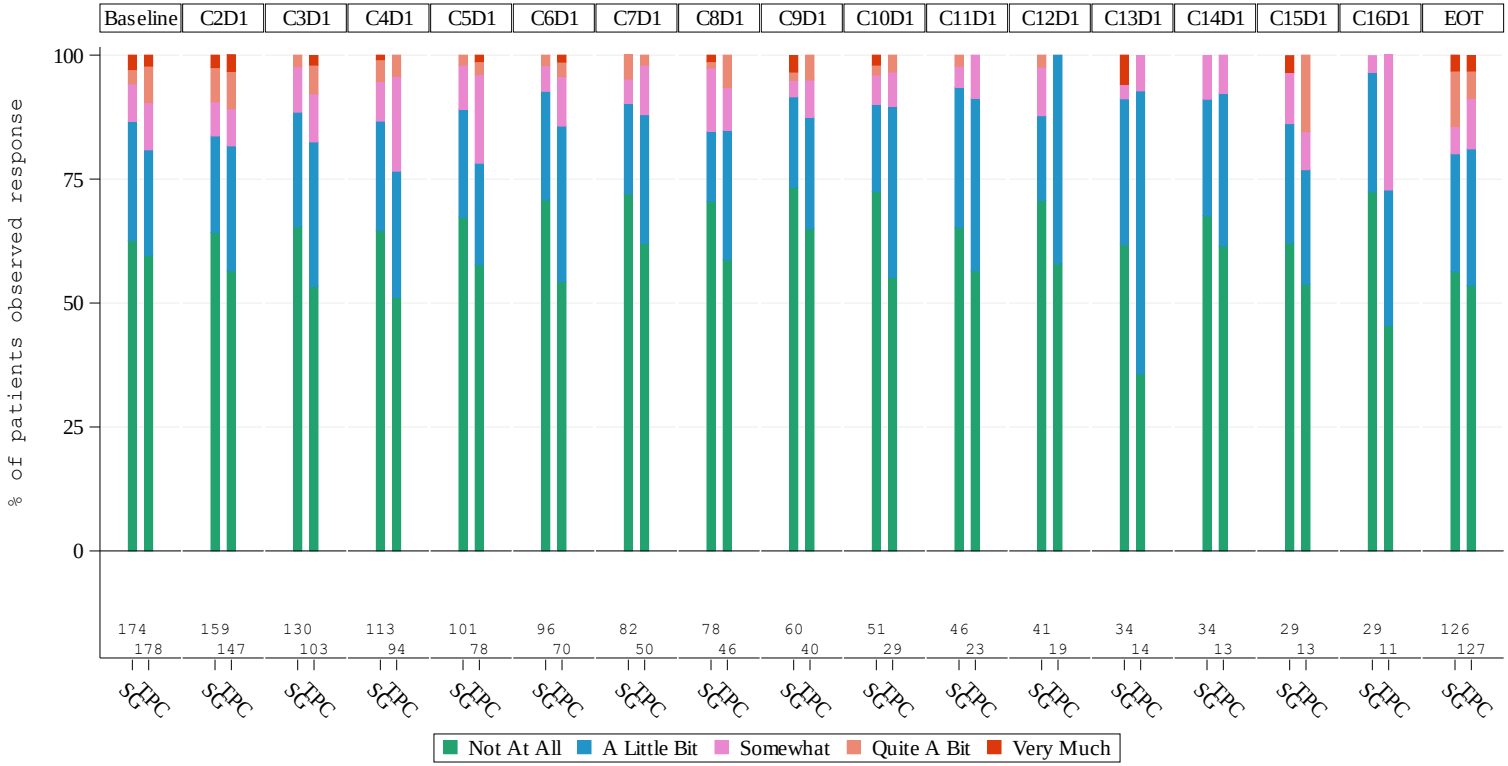
Figure 15.15.2.13
Distribution of Responses to the PRO-CTCAE Shortness of Breath Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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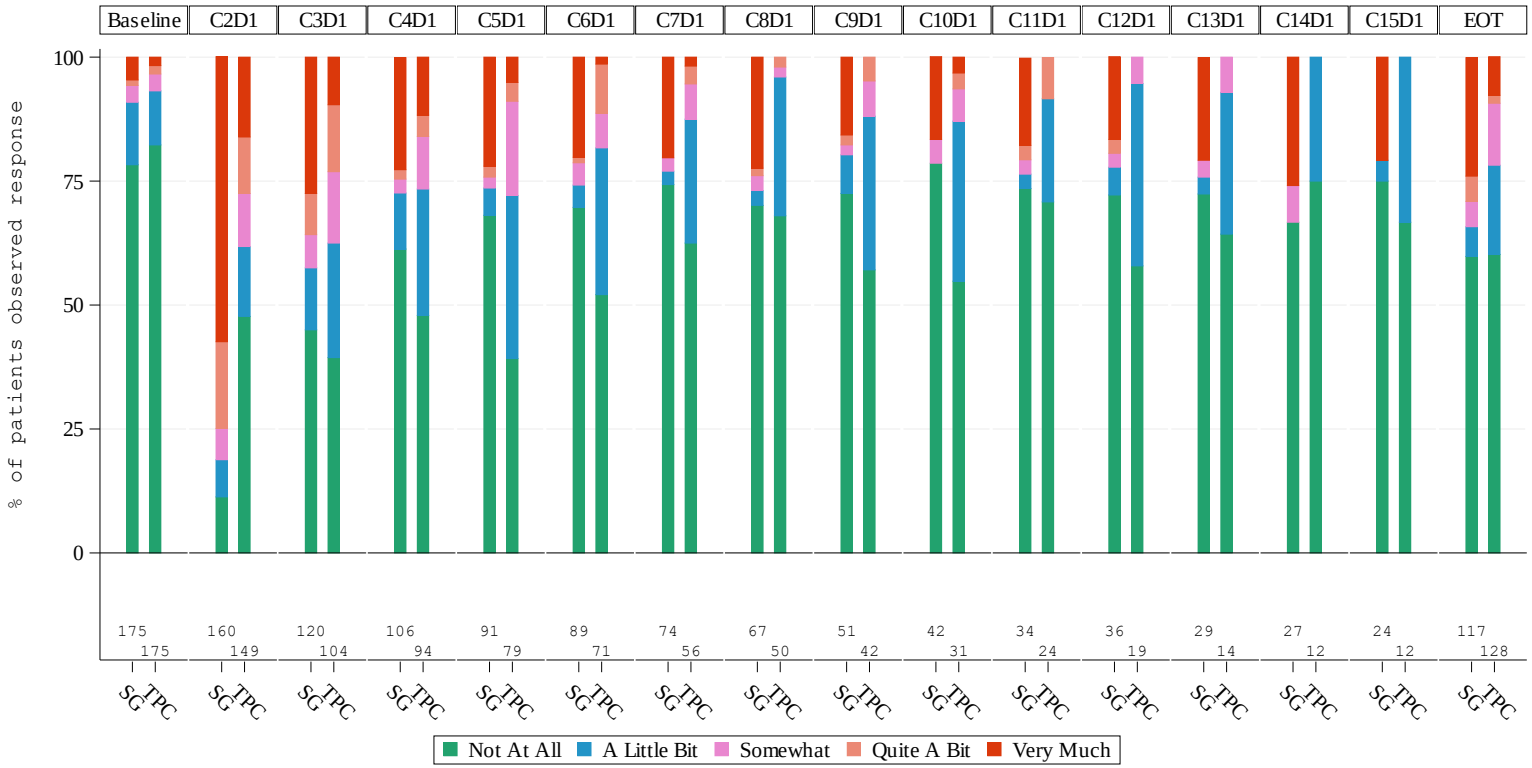
Figure 15.15.2.14
Distribution of Responses to the PRO-CTCAE Hair Loss Amount by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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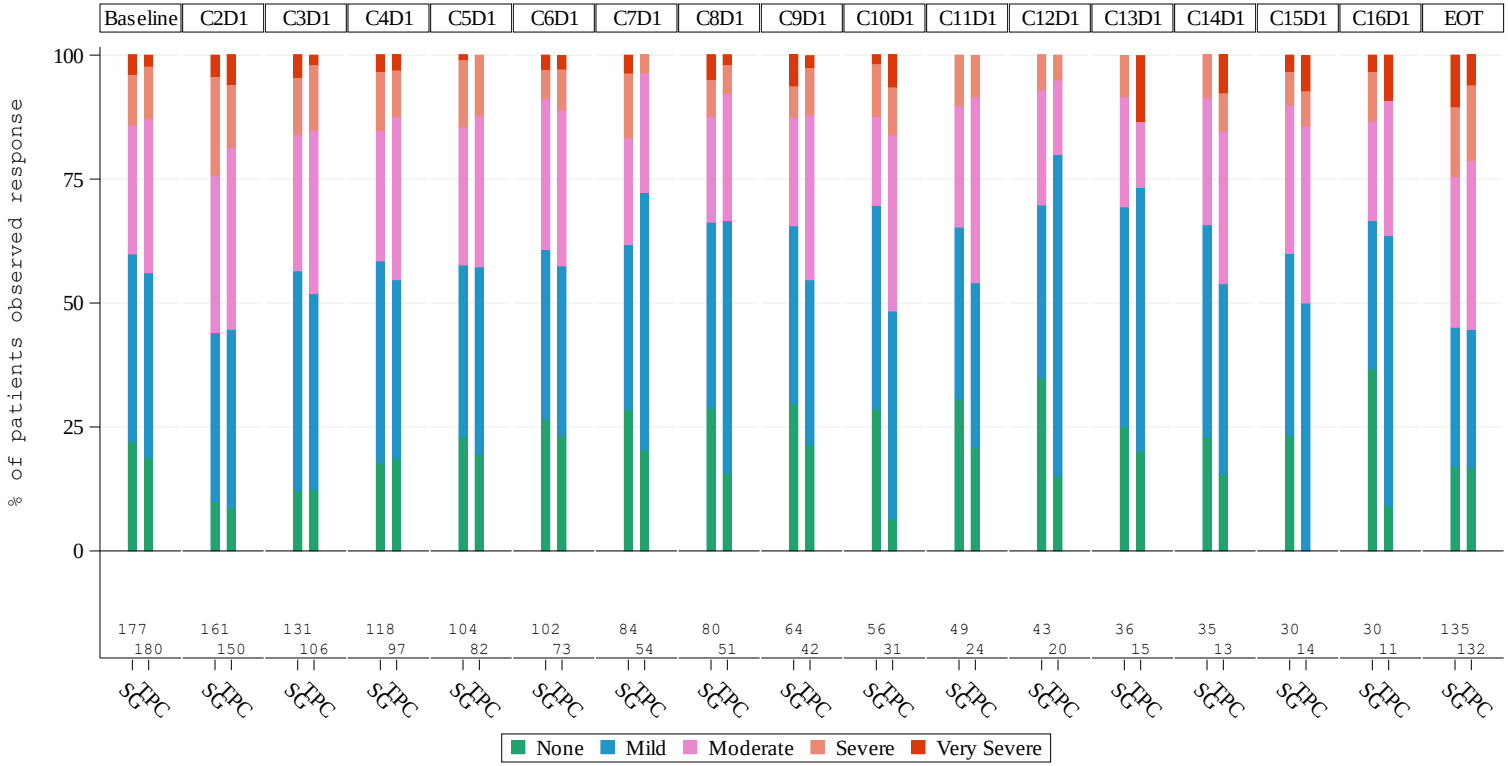
Figure 15.15.2.15
Distribution of Responses to the PRO-CTCAE Fatigue Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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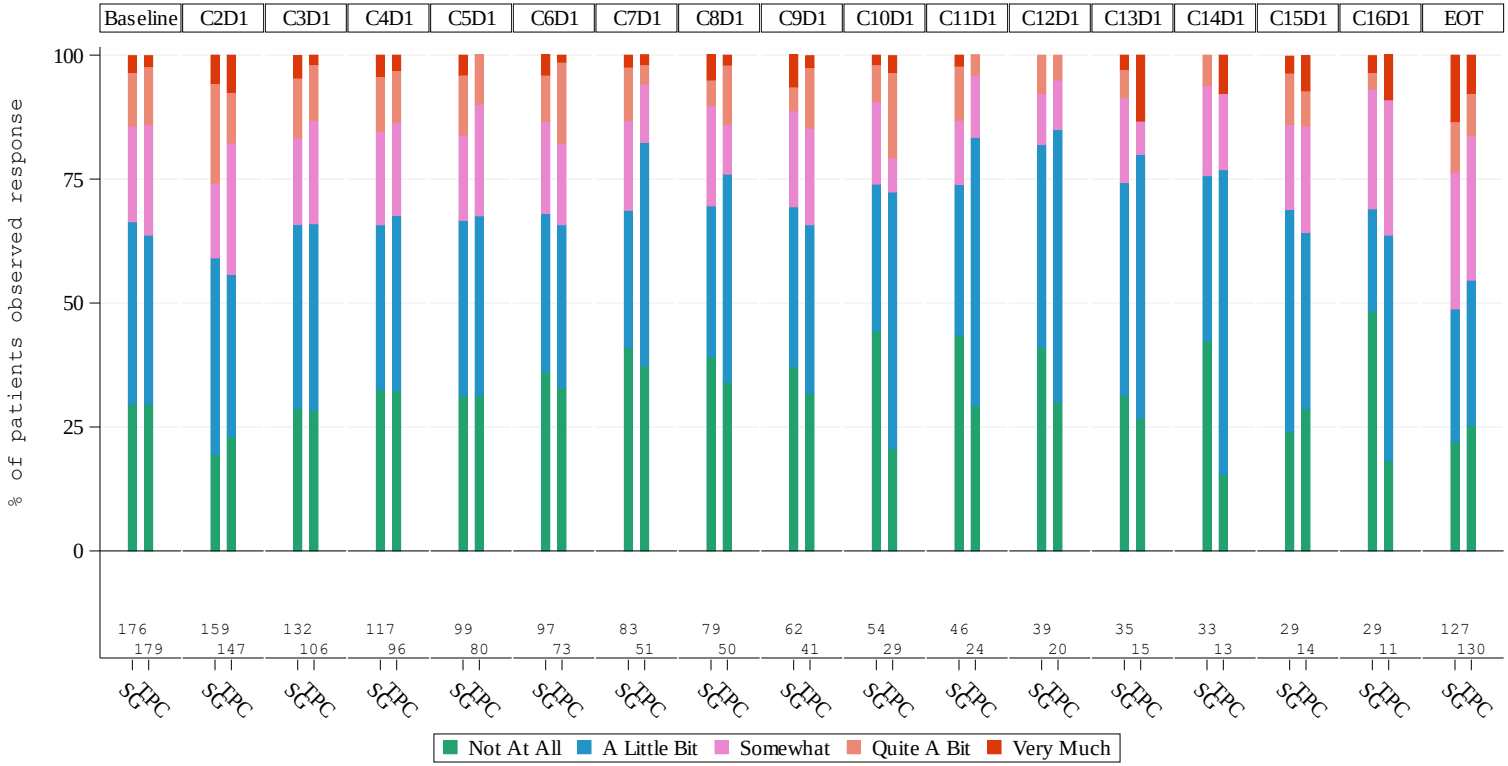
Figure 15.15.2.16
Distribution of Responses to the PRO-CTCAE Fatigue Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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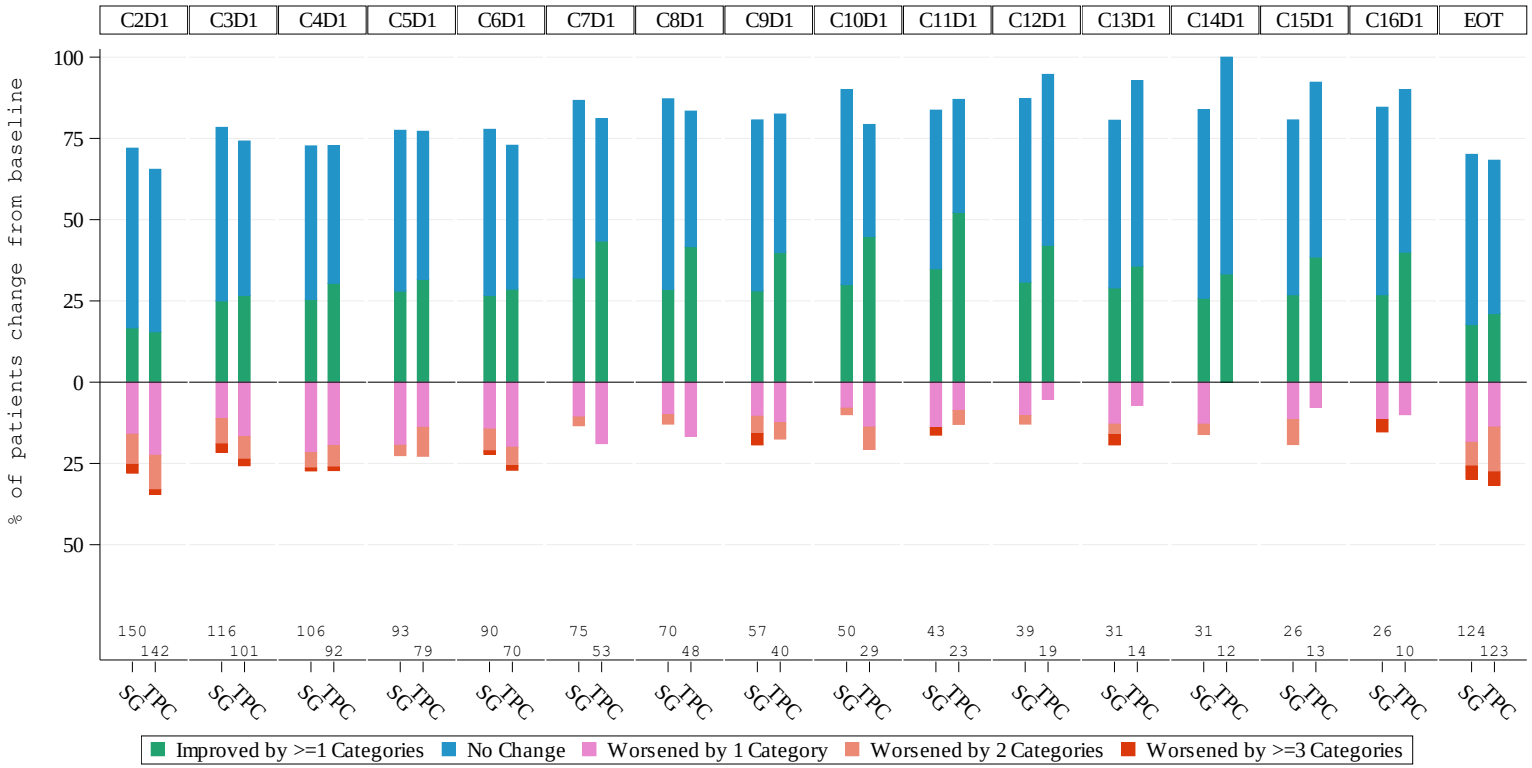
Figure 15.15.3.1
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Decreased Appetite Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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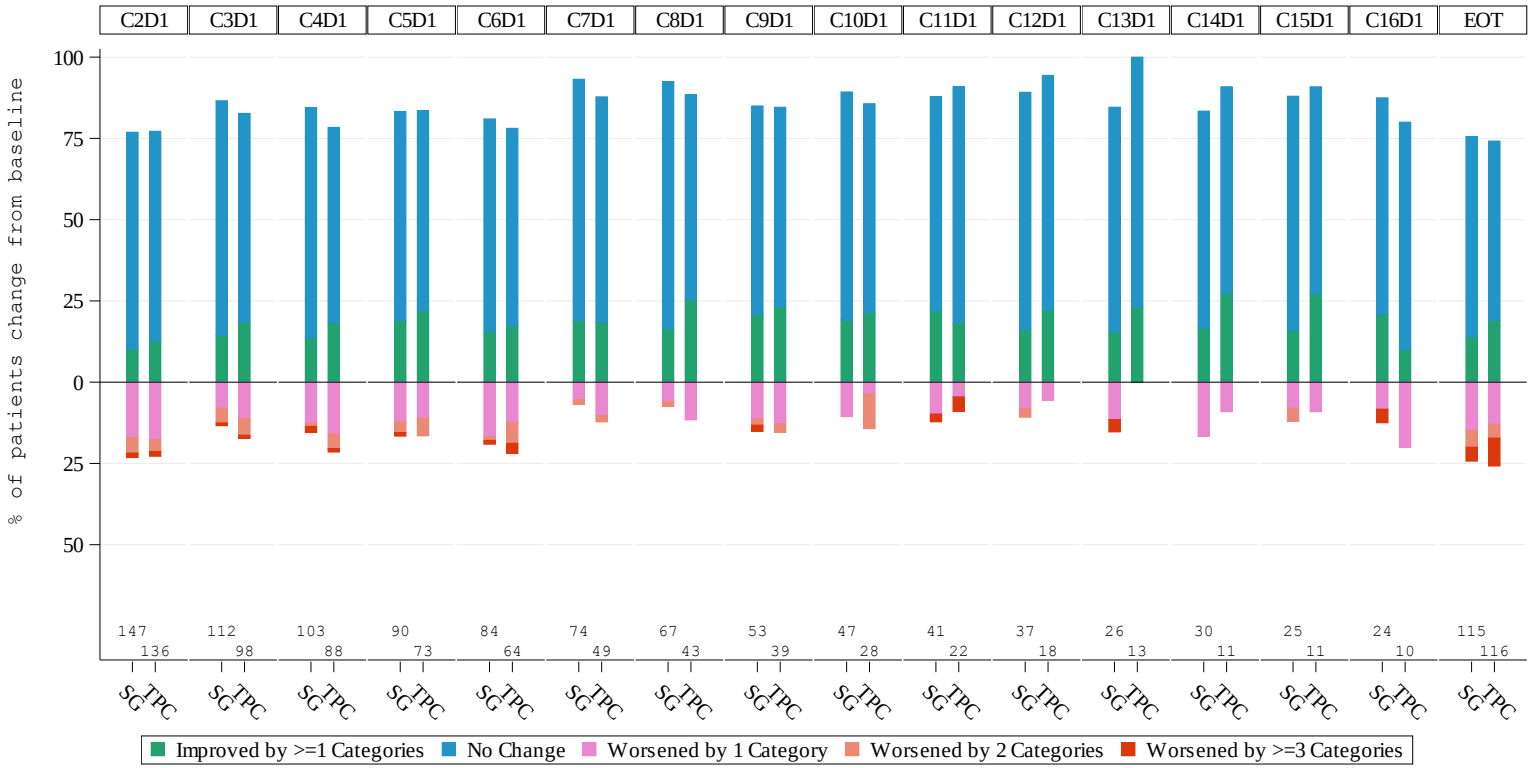
Figure 15.15.3.2
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Decreased Appetite Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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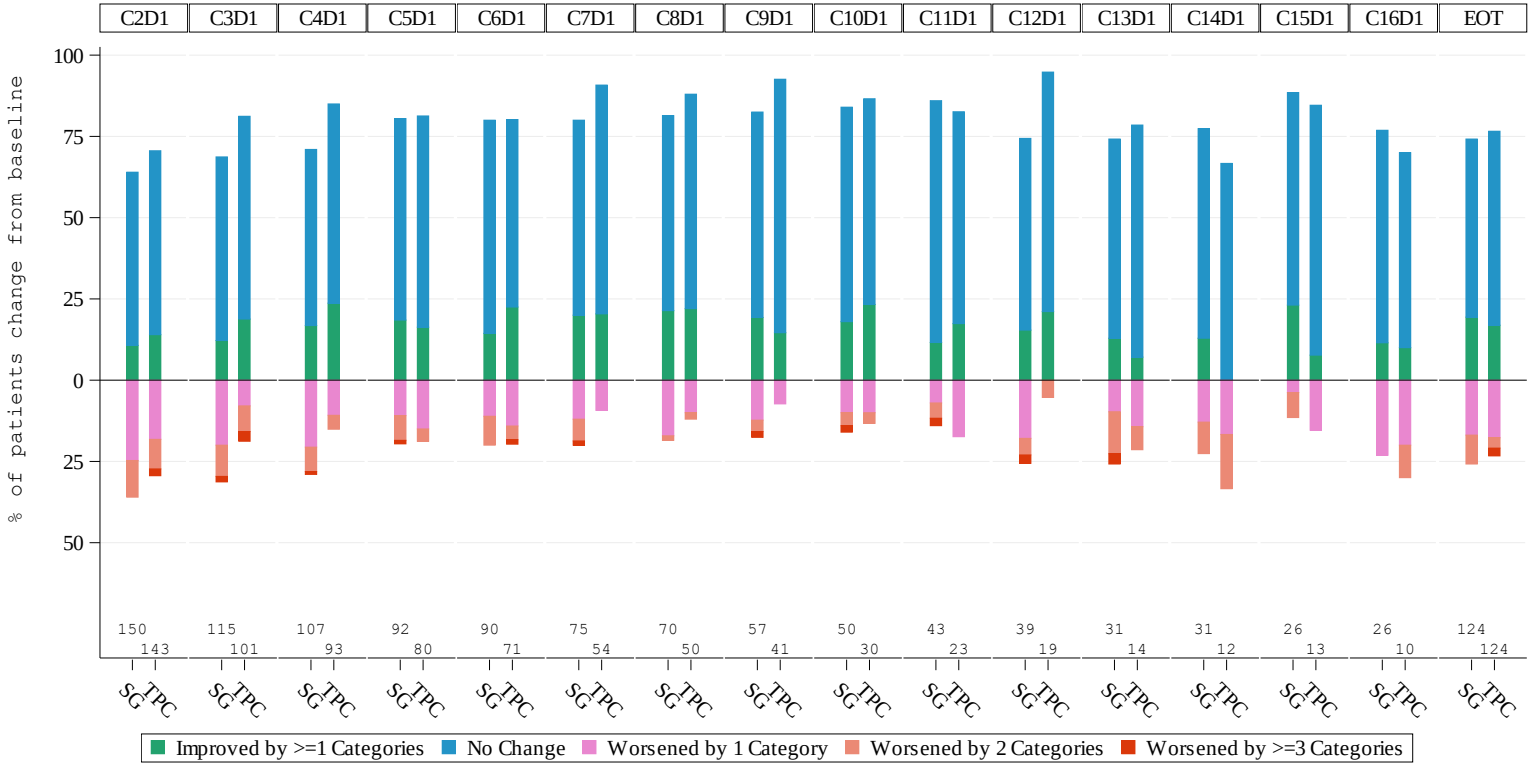
Figure 15.15.3.3
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Nausea Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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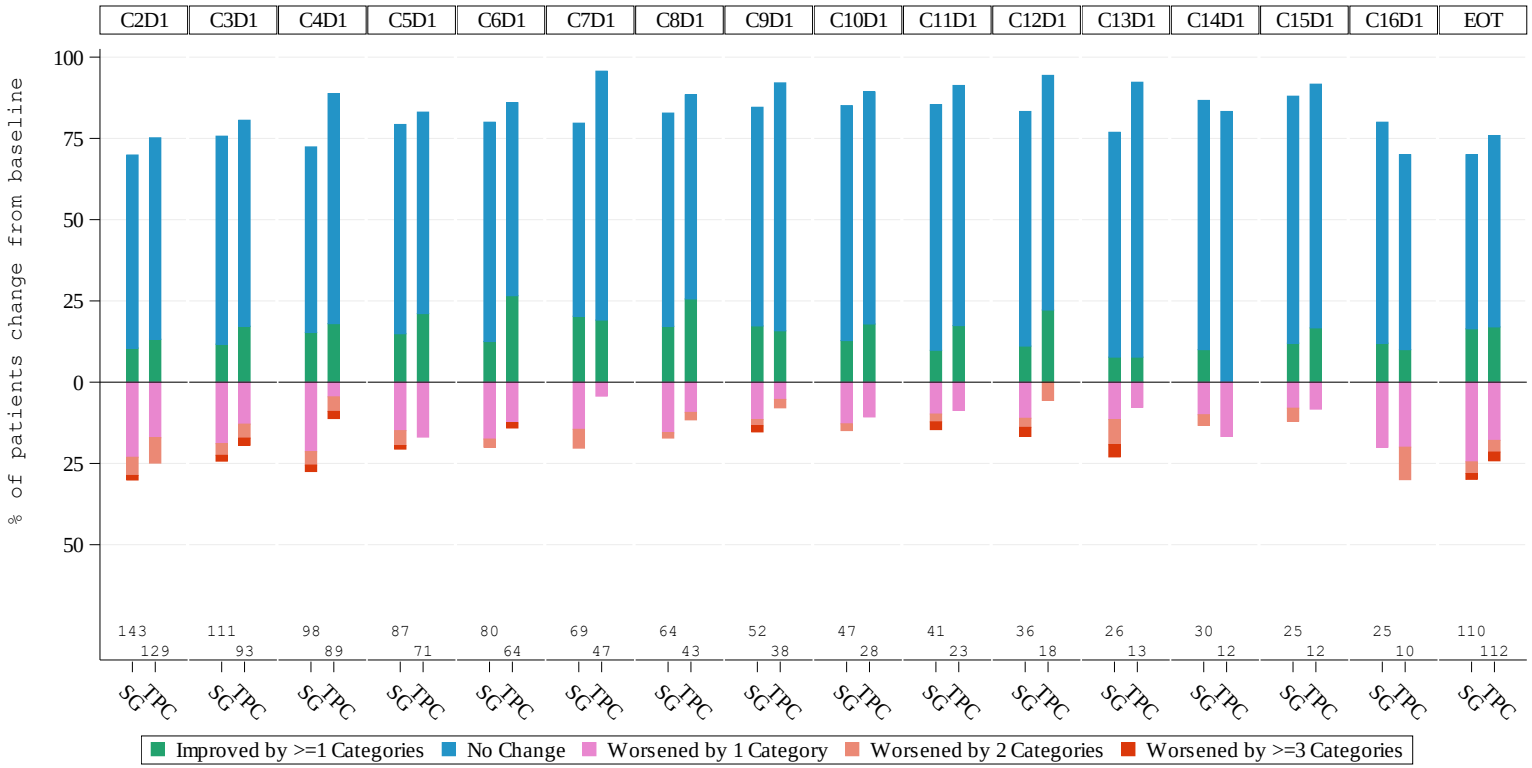
Figure 15.15.3.4
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Nausea Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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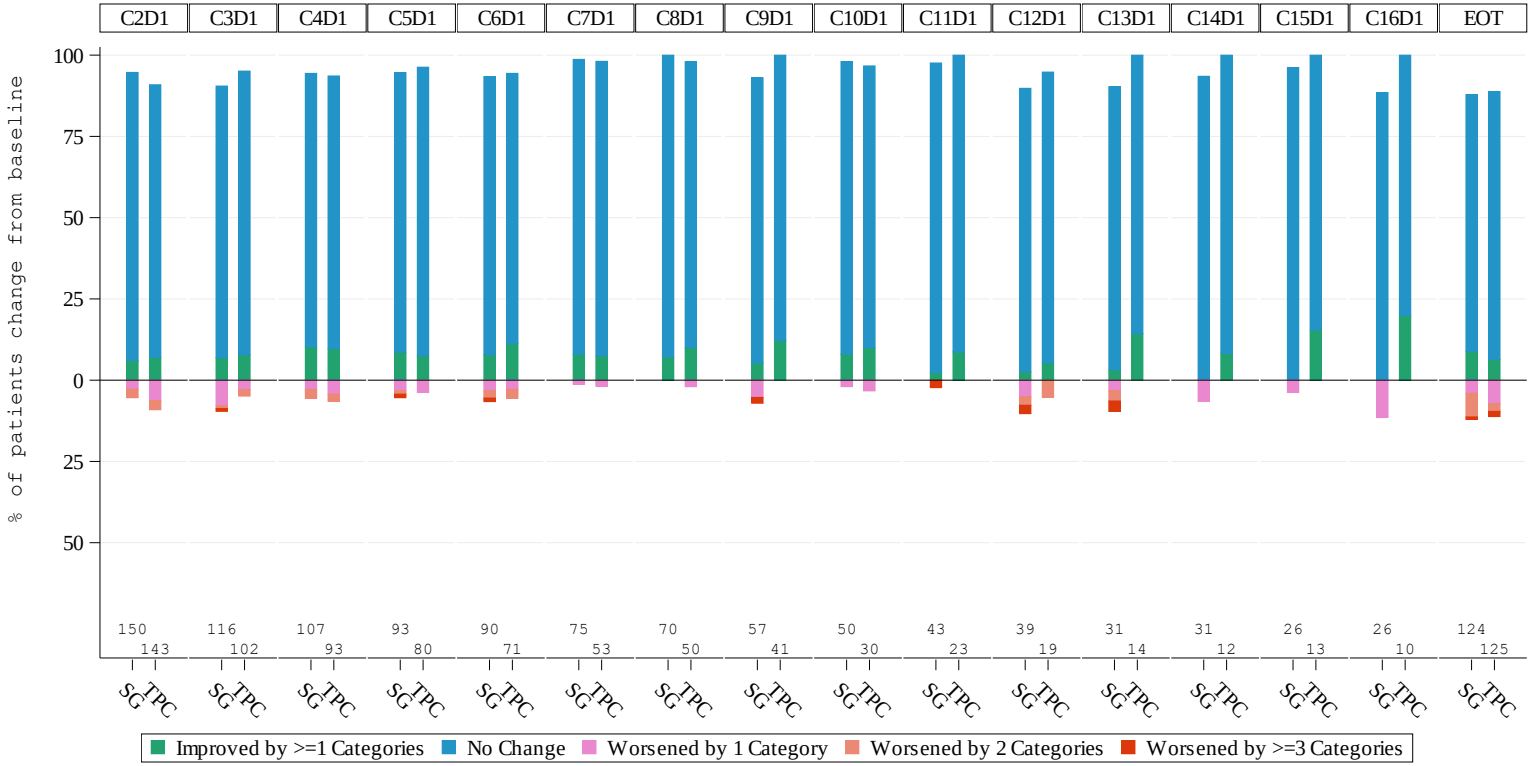
Figure 15.15.3.5
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Vomiting Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.

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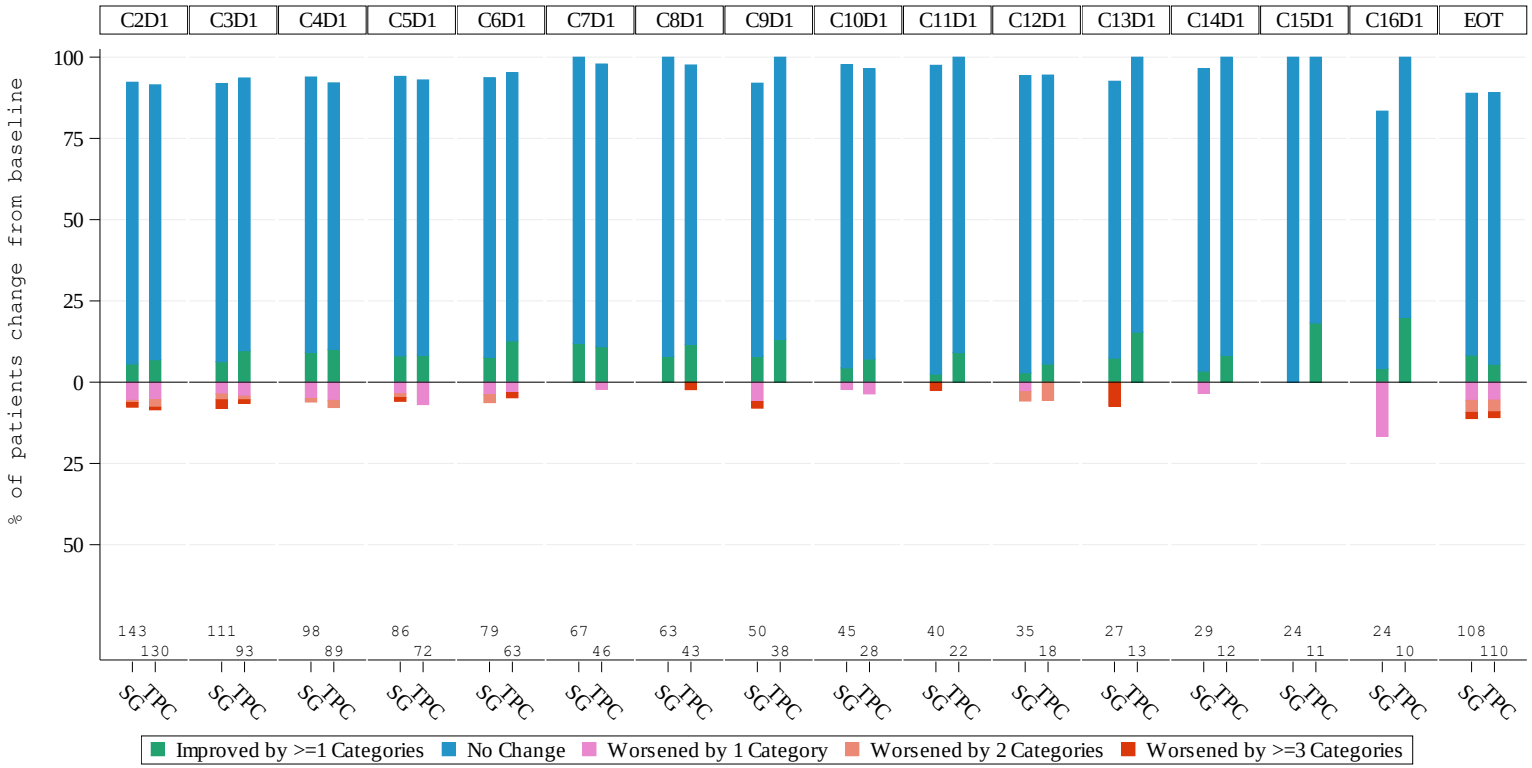
Figure 15.15.3.6
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Vomiting Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.

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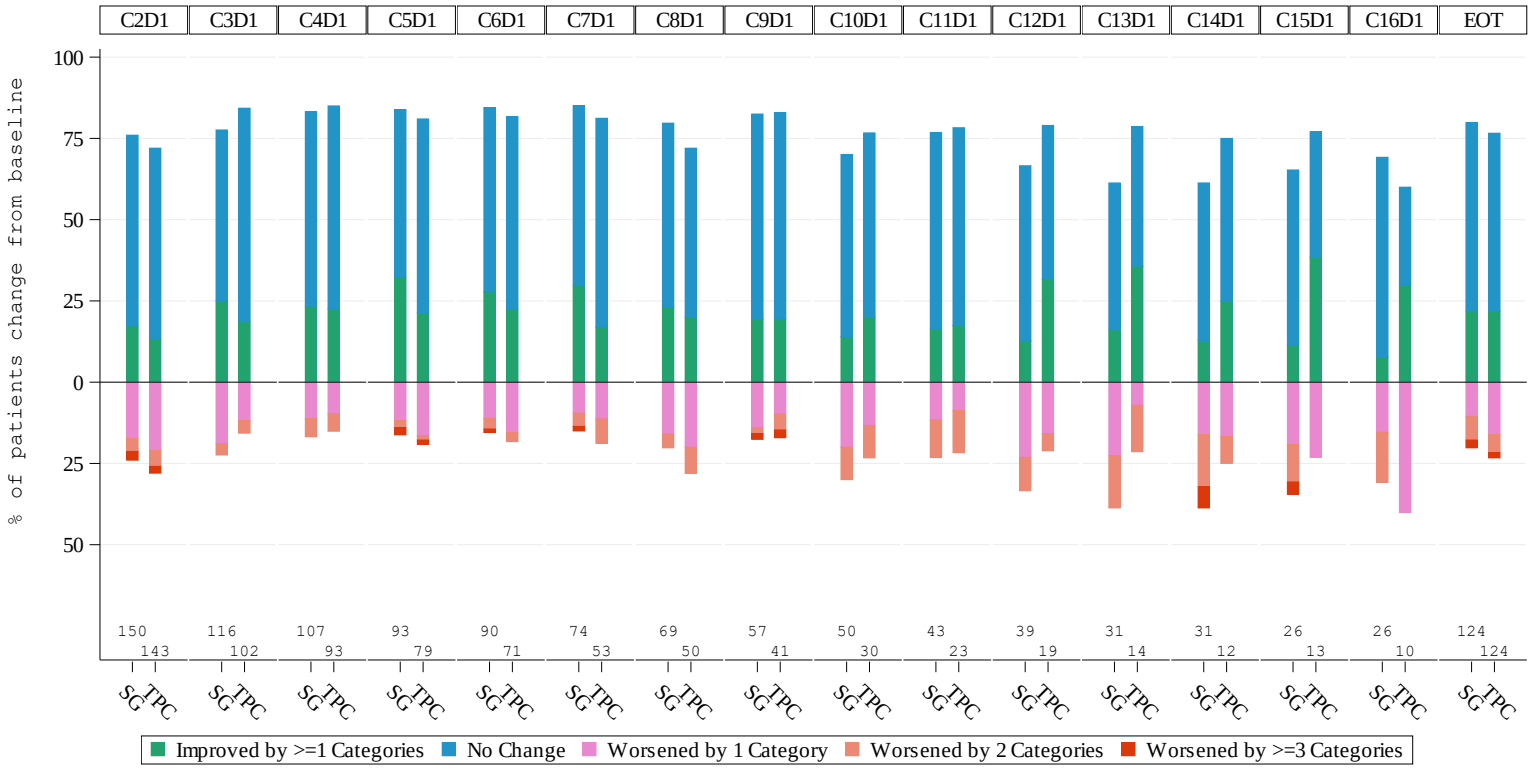
Figure 15.15.3.7
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Constipation Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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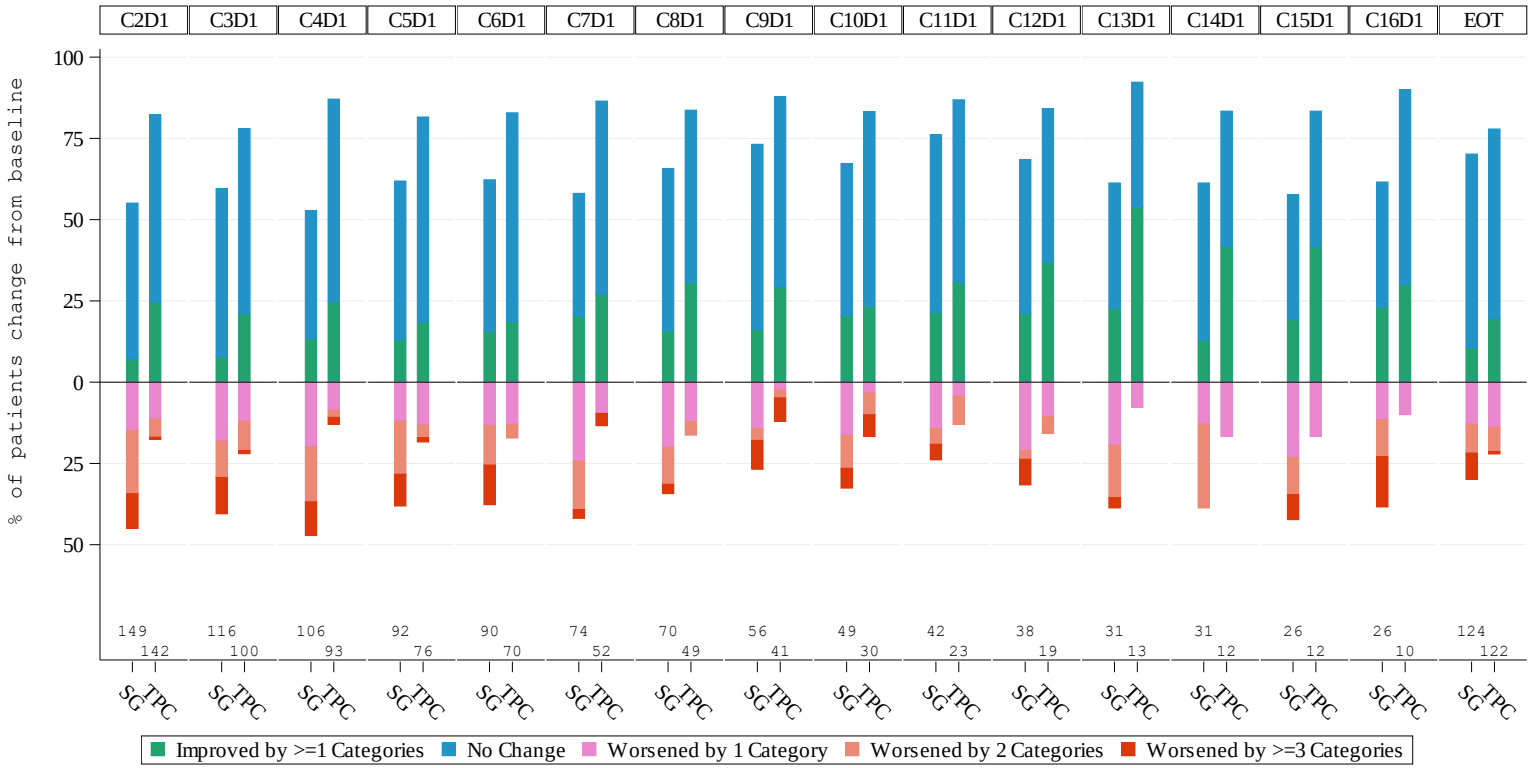
Figure 15.15.3.8
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Diarrhea Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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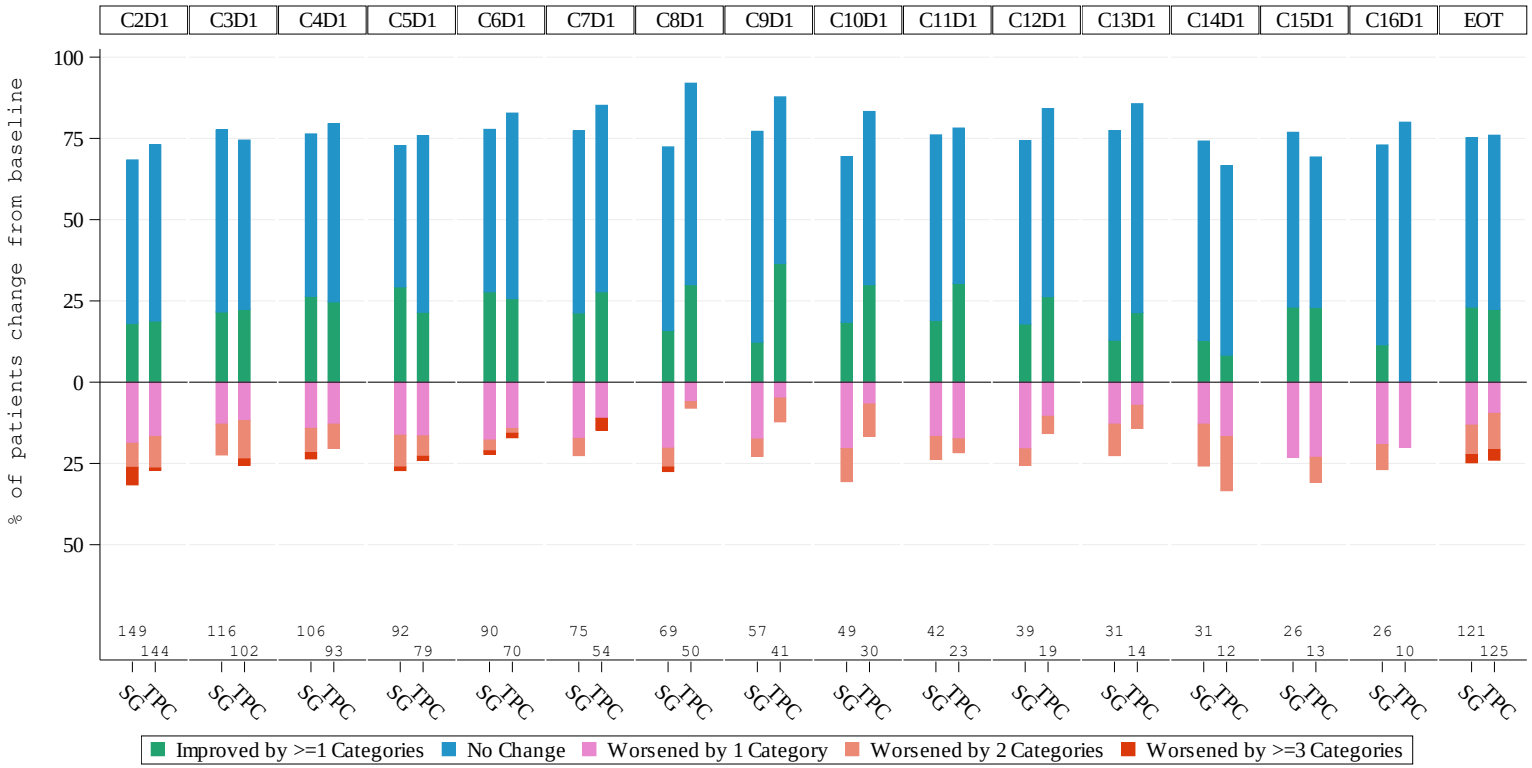
Figure 15.15.3.9
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Abdominal Pain Frequency by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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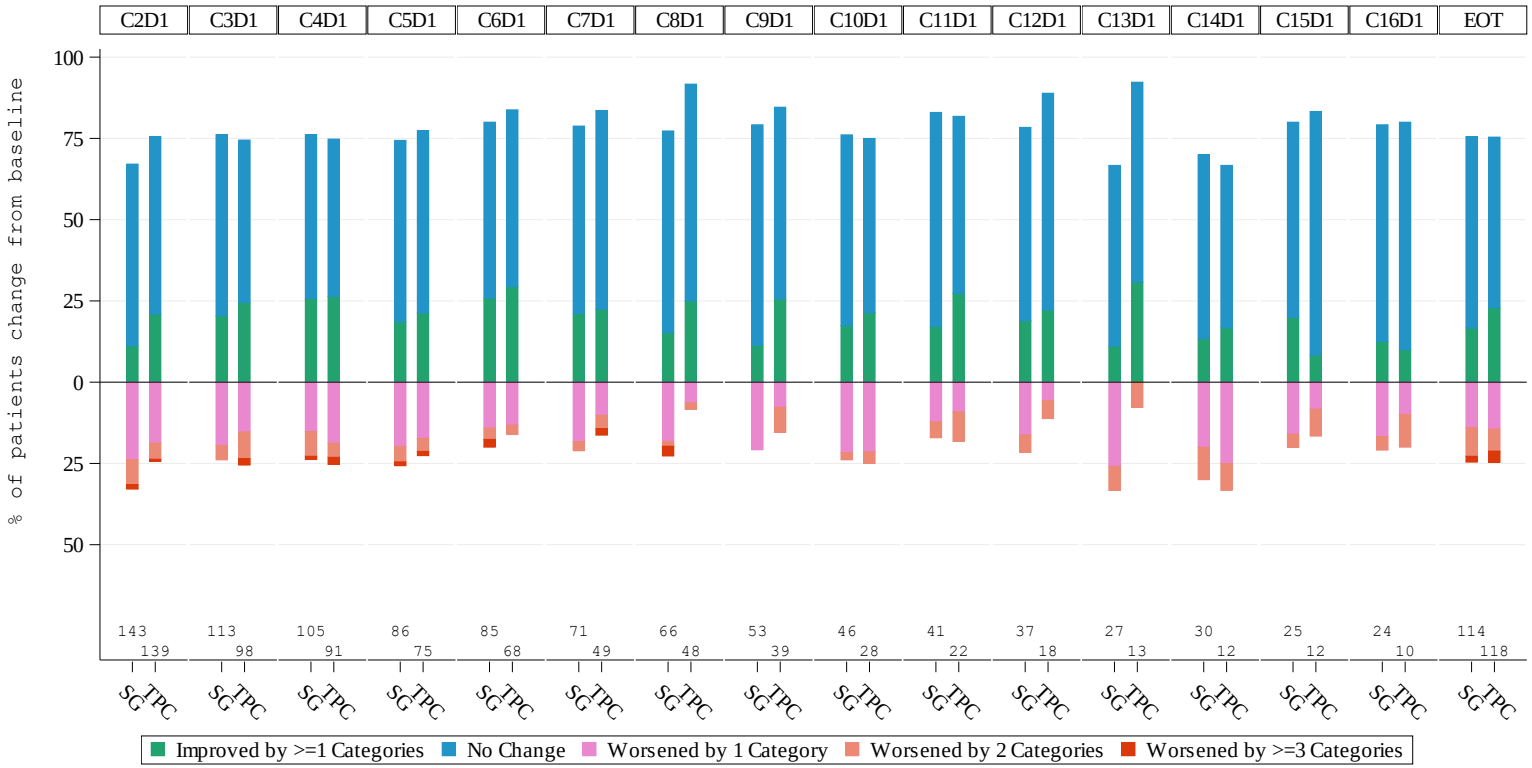
Figure 15.15.3.10
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Abdominal Pain Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.

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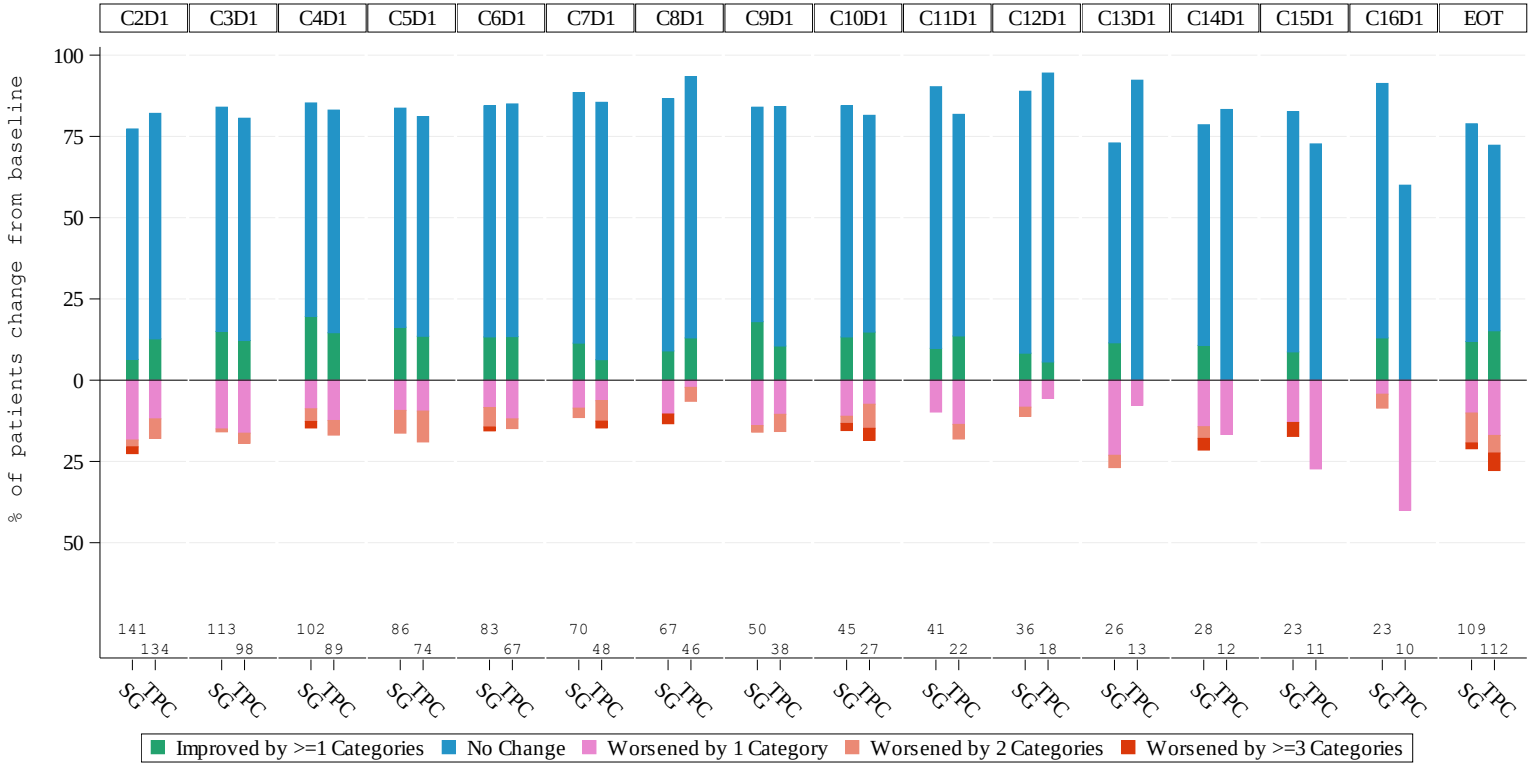
Figure 15.15.3.11
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Abdominal Pain Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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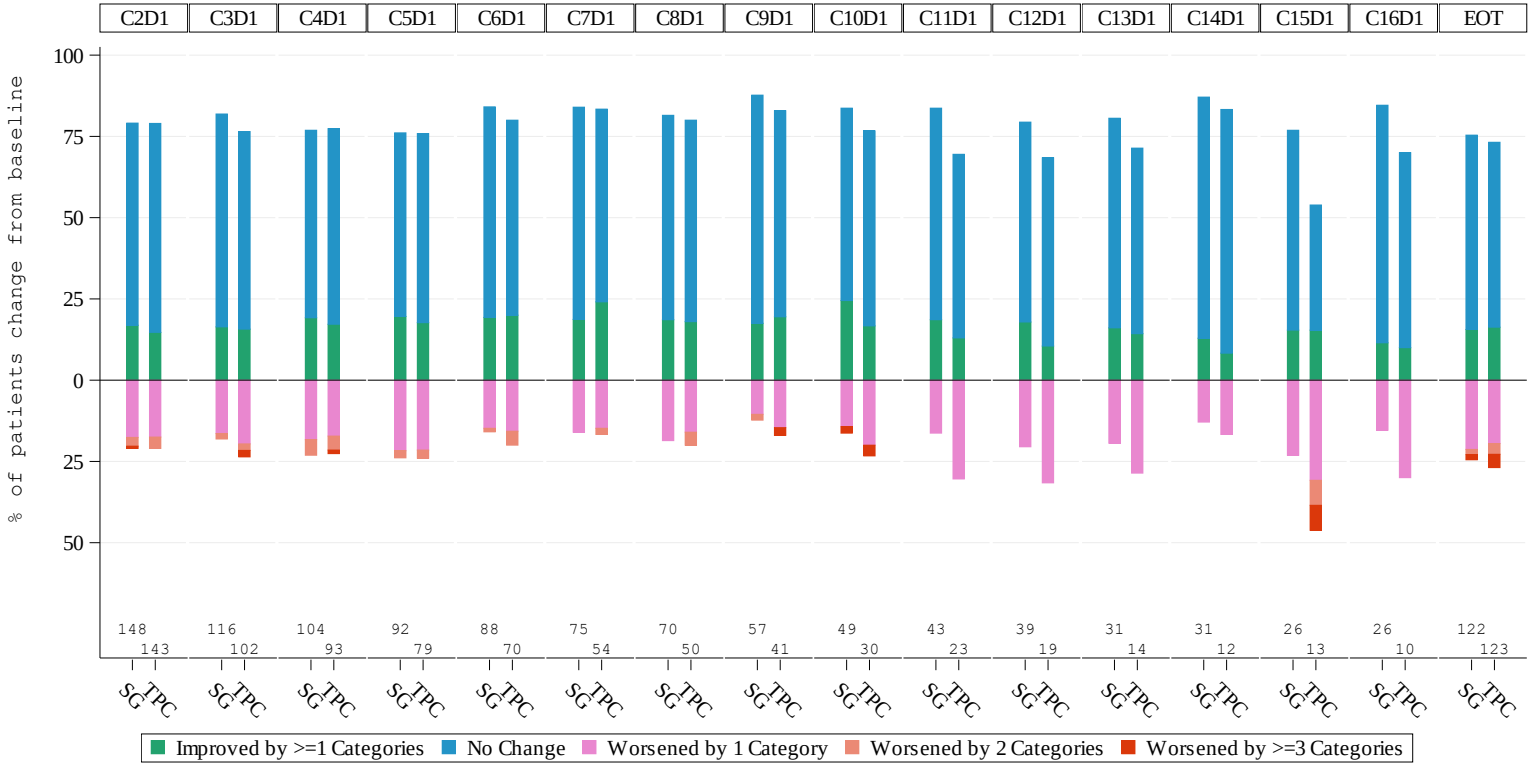
Figure 15.15.3.12
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Shortness of Breath Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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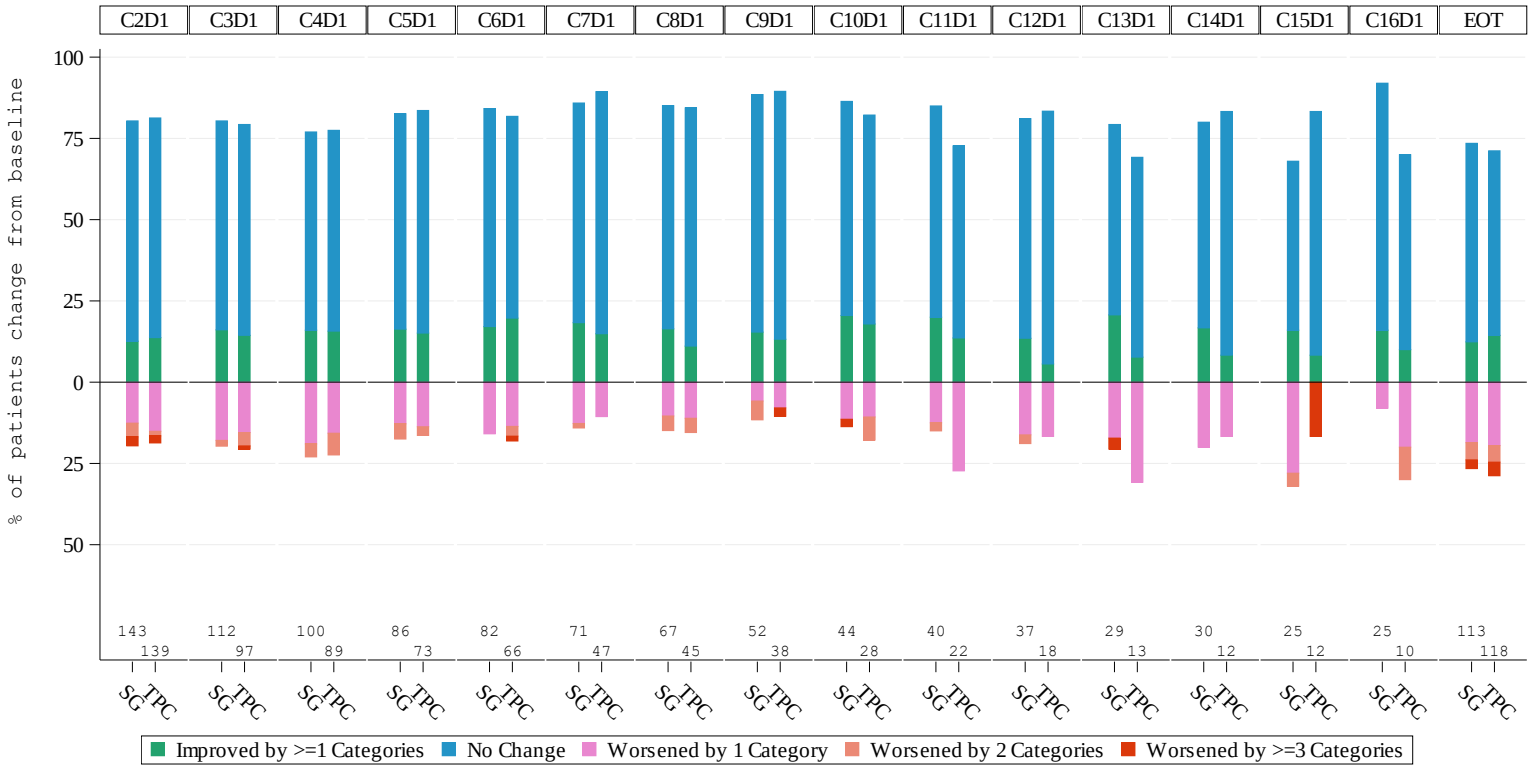
Figure 15.15.3.13
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Shortness of Breath Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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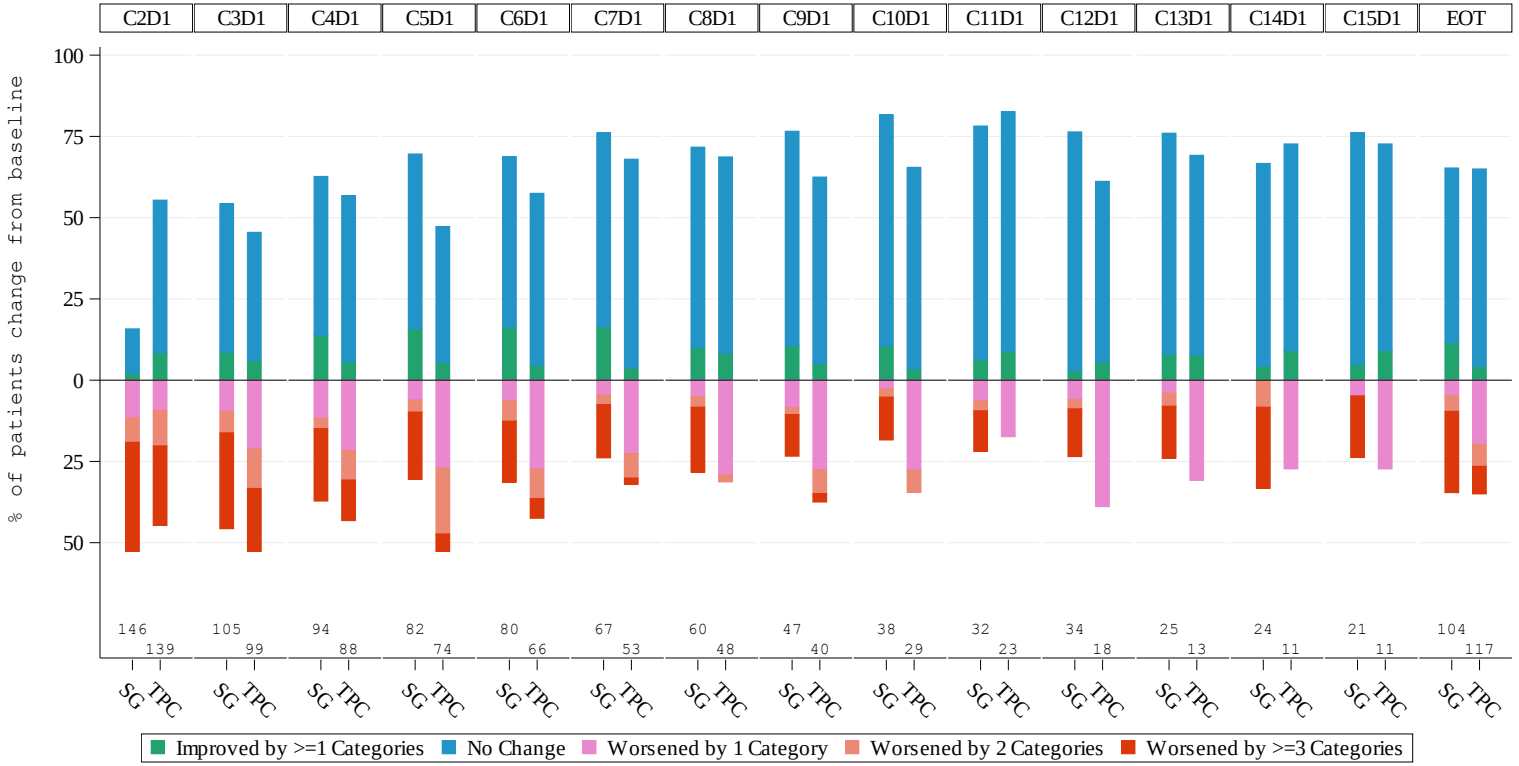
Figure 15.15.3.14
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Hair Loss Amount by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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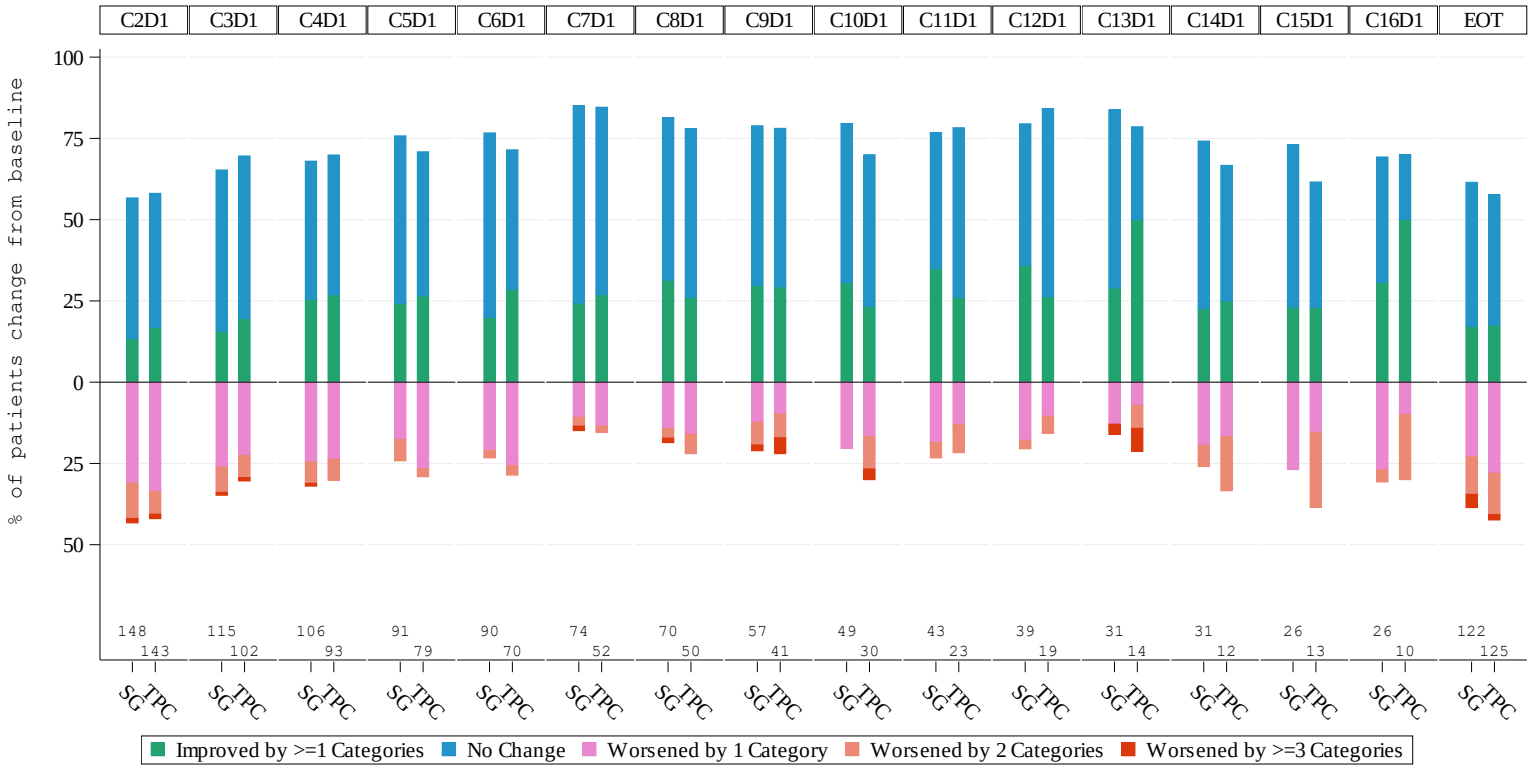
Figure 15.15.3.15
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Fatigue Severity by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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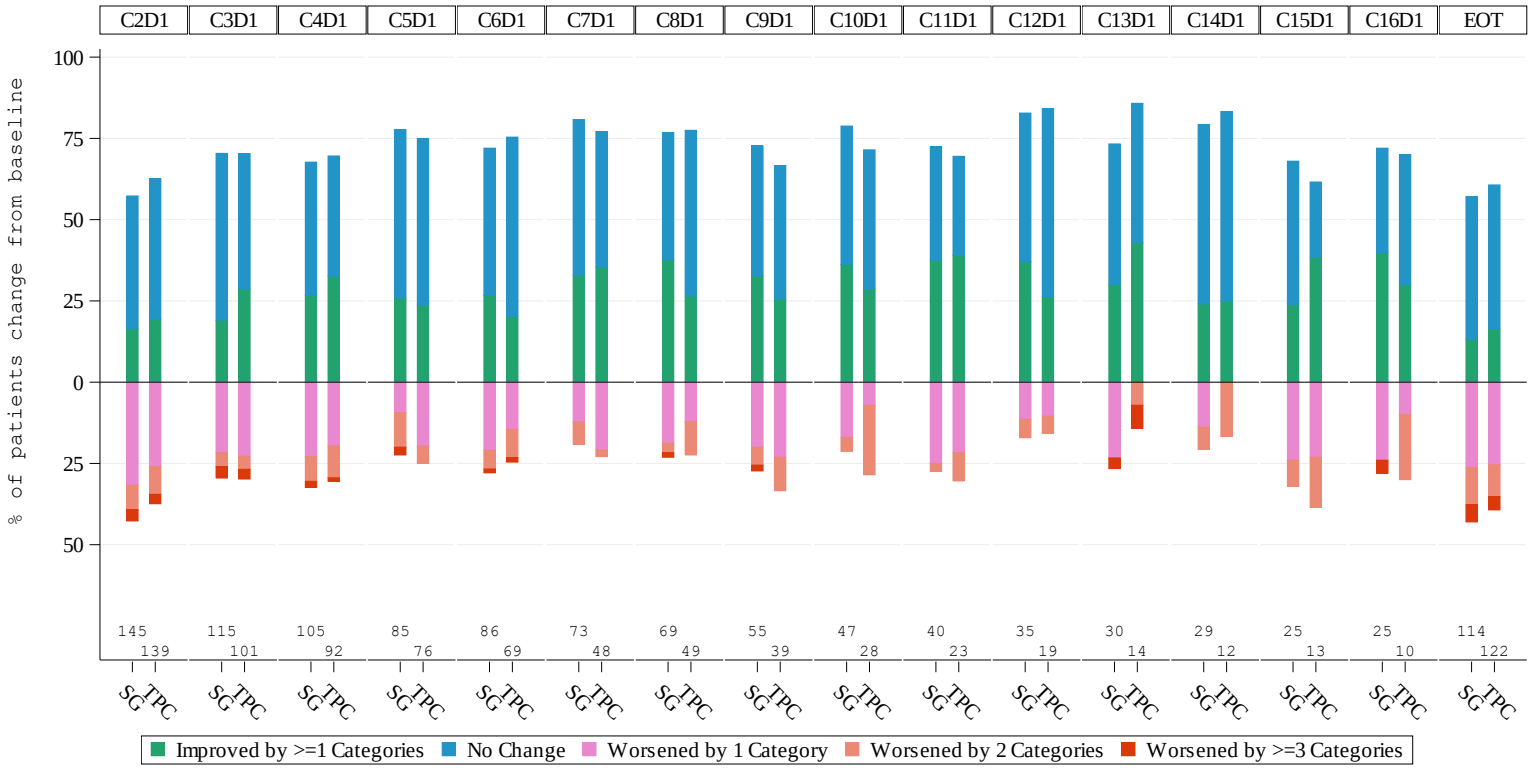
Figure 15.15.3.16
Distribution of Change in Response Categories from Baseline for the PRO-CTCAE Fatigue Interference by Visit and Treatment Group
Safety Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization



Note: "Safety population" is defined as all ITT subjects who have received at least one dose of study drug. The denominator for the percentage calculation in each response category is based on the number of subjects with non-missing score at a given post-baseline visit. SG = Sacituzumab Govitecan; PRO-CTCAE = PRO version of the Common Terminology Criteria for Adverse Events; TPC = Treatment Physician Choice.
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Anhang 4-G 6.3: Zeit bis zur Verschlechterung EQ-5D VAS

Table 15.15.6.2
Summary of Time to First HRQoL Worsening for EQ-5D VAS - Death Being Censored
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Patients With Events (%)	63 (37.5)	64 (39.5)	
	Patients Without Events (Censored) (%)	105 (62.5)	98 (60.5)	
	Median Time (months) [a]	11.8	7.0	
	95% CI	(6.9, NE)	(4.6, 12.7)	
	Log-rank p-value (Stratified) [b]			0.0730
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.724
	95% CI for Hazard Ratio			(0.507, 1.033)

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.

[c] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and thenumber of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.

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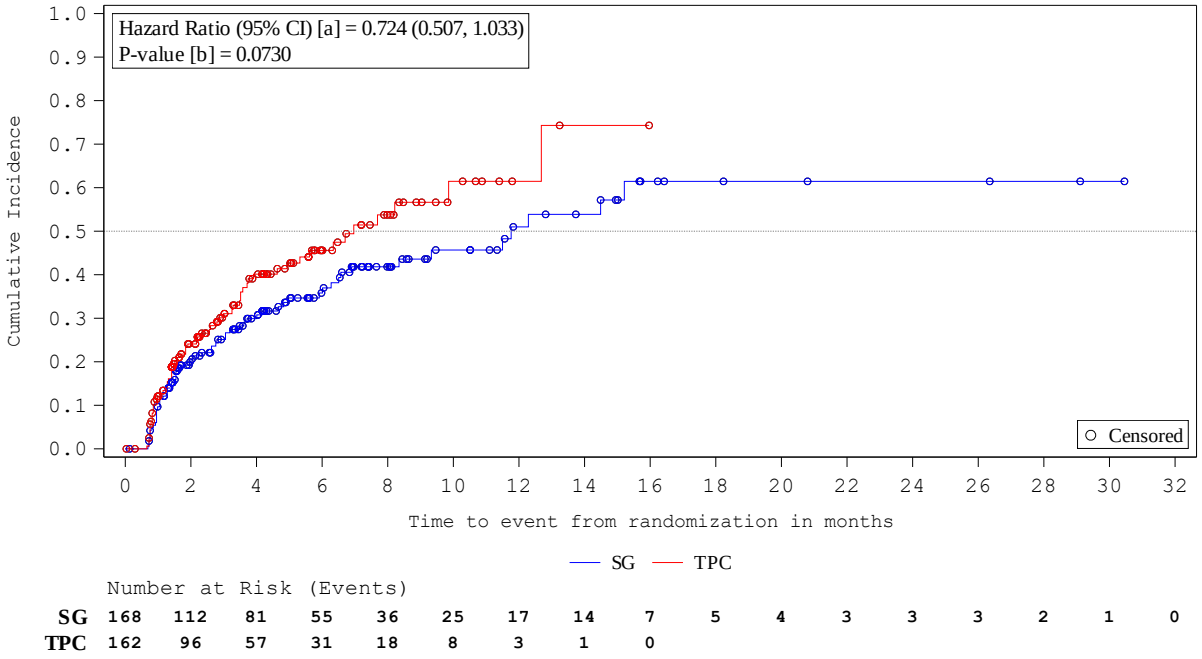
Figure 15.15.4.2
Kaplan-Meier Plot of Time to First Worsening in EQ-5D VAS by Treatment Group - Death Being Censored
EQ-5D-5L Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	168	112	81	55	36	25	17	14	7	5	4	3	3	3	2	1	0
TPC	162	96	57	31	18	8	3	1	0								

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline for EQ-5D VAS.
CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; HR = Hazard Ratio; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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Anhang 4-G 6.3.1: Subgruppenanalysen

Table 15.15.7.2.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Two Lines	Number of Patients	77	82	
		Patients With Events (%)	30 (39.0)	33 (40.2)	
		Patients Without Events (Censored) (%)	47 (61.0)	49 (59.8)	
		Median Time (months) [a]	11.5	8.2	
		95% CI	(6.9, 15.2)	(3.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.1279
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.675
		95% CI for Hazard Ratio			(0.406, 1.124)
	Three/Four Lines	Number of Patients	91	80	
		Patients With Events (%)	33 (36.3)	31 (38.8)	
		Patients Without Events (Censored) (%)	58 (63.7)	49 (61.3)	
		Median Time (months) [a]	12.3	7.0	
		95% CI	(5.0, NE)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.3307
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.783
		95% CI for Hazard Ratio			(0.477, 1.286)
		P-value of Subgroup*Treatment Interaction [d]			0.9855

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Visceral metastasis
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Yes	Number of Patients	161	155	
		Patients With Events (%)	62 (38.5)	62 (40.0)	
		Patients Without Events (Censored) (%)	99 (61.5)	93 (60.0)	
		Median Time (months) [a]	11.8	7.0	
		95% CI	(6.6, NE)	(4.6, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.1156
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.752
		95% CI for Hazard Ratio			(0.526, 1.075)
	No	Number of Patients	7	7	
		Patients With Events (%)	1 (14.3)	2 (28.6)	
		Patients Without Events (Censored) (%)	6 (85.7)	5 (71.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(1.6, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.4794
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.429
		95% CI for Hazard Ratio			(0.038, 4.795)
		P-value of Subgroup*Treatment Interaction [d]			0.5061

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Yes	Number of Patients	152	143	
		Patients With Events (%)	57 (37.5)	59 (41.3)	
		Patients Without Events (Censored) (%)	95 (62.5)	84 (58.7)	
		Median Time (months) [a]	12.3	7.0	
		95% CI	(6.6, NE)	(3.9, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.0623
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.705
		95% CI for Hazard Ratio			(0.486, 1.021)
	No	Number of Patients	16	19	
		Patients With Events (%)	6 (37.5)	5 (26.3)	
		Patients Without Events (Censored) (%)	10 (62.5)	14 (73.7)	
		Median Time (months) [a]	11.8	NE	
		95% CI	(1.7, NE)	(3.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.8727
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.102
		95% CI for Hazard Ratio			(0.334, 3.635)
		P-value of Subgroup*Treatment Interaction [d]			0.4297

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.
[a] Median Time is from Kaplan-Meier estimate.
[b] P-value is estimated from unstratified log-rank test.
[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.
[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.
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Table 15.15.7.2.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Age group
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	< 65 Years	Number of Patients	133	122	
		Patients With Events (%)	50 (37.6)	47 (38.5)	
		Patients Without Events (Censored) (%)	83 (62.4)	75 (61.5)	
		Median Time (months) [a]	11.8	7.0	
		95% CI	(6.9, 15.2)	(4.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.1619
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.749
		95% CI for Hazard Ratio			(0.499, 1.126)
	≥ 65 Years	Number of Patients	35	40	
		Patients With Events (%)	13 (37.1)	17 (42.5)	
		Patients Without Events (Censored) (%)	22 (62.9)	23 (57.5)	
		Median Time (months) [a]	NE	4.9	
		95% CI	(3.7, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.2533
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.657
		95% CI for Hazard Ratio			(0.318, 1.359)
		P-value of Subgroup*Treatment Interaction [d]			0.6837

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Race
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	White	Number of Patients	120	110	
		Patients With Events (%)	49 (40.8)	46 (41.8)	
		Patients Without Events (Censored) (%)	71 (59.2)	64 (58.2)	
		Median Time (months) [a]	11.5	6.3	
		95% CI	(5.9, NE)	(3.5, 9.9)	
		Log-rank p-value (Unstratified) [b]			0.1098
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.716
		95% CI for Hazard Ratio			(0.474, 1.082)
	Non-White	Number of Patients	12	15	
		Patients With Events (%)	2 (16.7)	6 (40.0)	
		Patients Without Events (Censored) (%)	10 (83.3)	9 (60.0)	
		Median Time (months) [a]	NE	5.6	
		95% CI	(1.0, NE)	(1.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.3051
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.445
		95% CI for Hazard Ratio			(0.090, 2.205)
		P-value of Subgroup*Treatment Interaction [d]			0.4739

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Baseline ECOG status
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	0	Number of Patients	75	77	
		Patients With Events (%)	27 (36.0)	31 (40.3)	
		Patients Without Events (Censored) (%)	48 (64.0)	46 (59.7)	
		Median Time (months) [a]	14.5	7.0	
		95% CI	(6.9, NE)	(3.5, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.0271
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.547
		95% CI for Hazard Ratio			(0.317, 0.942)
	1	Number of Patients	93	85	
		Patients With Events (%)	36 (38.7)	33 (38.8)	
		Patients Without Events (Censored) (%)	57 (61.3)	52 (61.2)	
		Median Time (months) [a]	9.3	6.3	
		95% CI	(4.7, NE)	(3.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.6370
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.893
		95% CI for Hazard Ratio			(0.556, 1.433)
		P-value of Subgroup*Treatment Interaction [d]			0.3223

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Geographic region
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Europe	Number of Patients	101	103	
		Patients With Events (%)	40 (39.6)	43 (41.7)	
		Patients Without Events (Censored) (%)	61 (60.4)	60 (58.3)	
		Median Time (months) [a]	11.8	7.7	
		95% CI	(6.0, 15.2)	(3.7, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.2363
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.770
		95% CI for Hazard Ratio			(0.498, 1.190)
	North America	Number of Patients	67	59	
		Patients With Events (%)	23 (34.3)	21 (35.6)	
		Patients Without Events (Censored) (%)	44 (65.7)	38 (64.4)	
		Median Time (months) [a]	NE	6.3	
		95% CI	(6.6, NE)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.2757
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.717
		95% CI for Hazard Ratio			(0.393, 1.310)
		P-value of Subgroup*Treatment Interaction [d]			0.5823

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Prior CDK inhibitor treatment duration
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	≤ 12 Months	Number of Patients	94	98	
		Patients With Events (%)	35 (37.2)	34 (34.7)	
		Patients Without Events (Censored) (%)	59 (62.8)	64 (65.3)	
		Median Time (months) [a]	14.5	8.2	
		95% CI	(6.5, NE)	(5.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.3514
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.795
		95% CI for Hazard Ratio			(0.489, 1.291)
	> 12 Months	Number of Patients	71	62	
		Patients With Events (%)	28 (39.4)	29 (46.8)	
		Patients Without Events (Censored) (%)	43 (60.6)	33 (53.2)	
		Median Time (months) [a]	8.3	5.6	
		95% CI	(5.9, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.1844
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.704
		95% CI for Hazard Ratio			(0.417, 1.187)
		P-value of Subgroup*Treatment Interaction [d]			0.7133

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Early relapse
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Yes	Number of Patients	11	9	
		Patients With Events (%)	5 (45.5)	3 (33.3)	
		Patients Without Events (Censored) (%)	6 (54.5)	6 (66.7)	
		Median Time (months) [a]	6.9	NE	
		95% CI	(1.1, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.4558
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.541
		95% CI for Hazard Ratio			(0.105, 2.779)
	No	Number of Patients	150	150	
		Patients With Events (%)	53 (35.3)	59 (39.3)	
		Patients Without Events (Censored) (%)	97 (64.7)	91 (60.7)	
		Median Time (months) [a]	12.3	7.0	
		95% CI	(8.3, NE)	(4.9, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.0870
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.721
		95% CI for Hazard Ratio			(0.495, 1.052)
		P-value of Subgroup*Treatment Interaction [d]			0.9933

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Chemotherapy in neo/adjuvant setting
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Yes	Number of Patients	100	106	
		Patients With Events (%)	40 (40.0)	39 (36.8)	
		Patients Without Events (Censored) (%)	60 (60.0)	67 (63.2)	
		Median Time (months) [a]	11.5	7.7	
		95% CI	(6.3, 15.2)	(3.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.3577
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.809
		95% CI for Hazard Ratio			(0.515, 1.273)
	No	Number of Patients	68	56	
		Patients With Events (%)	23 (33.8)	25 (44.6)	
		Patients Without Events (Censored) (%)	45 (66.2)	31 (55.4)	
		Median Time (months) [a]	NE	6.3	
		95% CI	(4.7, NE)	(3.5, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.1053
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.629
		95% CI for Hazard Ratio			(0.357, 1.110)
		P-value of Subgroup*Treatment Interaction [d]			0.4254

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.2.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Trop2 H-Score
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	<100	Number of Patients	55	60	
		Patients With Events (%)	21 (38.2)	21 (35.0)	
		Patients Without Events (Censored) (%)	34 (61.8)	39 (65.0)	
		Median Time (months) [a]	9.3	7.7	
		95% CI	(6.3, NE)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.9648
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.014
		95% CI for Hazard Ratio			(0.551, 1.865)
	≥100 to ≤200	Number of Patients	58	57	
		Patients With Events (%)	21 (36.2)	24 (42.1)	
		Patients Without Events (Censored) (%)	37 (63.8)	33 (57.9)	
		Median Time (months) [a]	11.8	3.7	
		95% CI	(5.9, NE)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.0352
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.528
		95% CI for Hazard Ratio			(0.288, 0.968)
	>200	Number of Patients	34	25	
		Patients With Events (%)	13 (38.2)	11 (44.0)	
		Patients Without Events (Censored) (%)	21 (61.8)	14 (56.0)	
		Median Time (months) [a]	15.2	9.9	
		95% CI	(3.7, NE)	(2.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.4513
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.732
		95% CI for Hazard Ratio			(0.323, 1.656)
		P-value of Subgroup*Treatment Interaction [d]			0.2841

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Capecitabine	Number of Patients	19	20	
		Patients With Events (%)	4 (21.1)	7 (35.0)	
		Patients Without Events (Censored) (%)	15 (78.9)	13 (65.0)	
		Median Time (months) [a]	NE	NE	
		95% CI	(2.0, NE)	(2.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.5380
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.681
		95% CI for Hazard Ratio			(0.199, 2.329)
	Eribulin	Number of Patients	105	107	
		Patients With Events (%)	39 (37.1)	51 (47.7)	
		Patients Without Events (Censored) (%)	66 (62.9)	56 (52.3)	
		Median Time (months) [a]	14.5	6.3	
		95% CI	(6.6, NE)	(3.6, 9.9)	
		Log-rank p-value (Unstratified) [b]			0.0230
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.616
		95% CI for Hazard Ratio			(0.403, 0.941)
	Vinorelbine	Number of Patients	44	35	
		Patients With Events (%)	20 (45.5)	6 (17.1)	
		Patients Without Events (Censored) (%)	24 (54.5)	29 (82.9)	
		Median Time (months) [a]	8.3	6.7	
		95% CI	(3.1, NE)	(2.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.5054
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.371
		95% CI for Hazard Ratio			(0.537, 3.499)
		P-value of Subgroup*Treatment Interaction [d]			0.1773

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.2.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EQ-5D VAS by Subgroup - Baseline documented target or non-target liver lesions
EQ-5D-5L Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=175)	TPC (N=164)	Treatment Comparison
EQ-5D VAS	Yes	Number of Patients	148	142	
		Patients With Events (%)	57 (38.5)	57 (40.1)	
		Patients Without Events (Censored) (%)	91 (61.5)	85 (59.9)	
		Median Time (months) [a]	11.8	6.7	
		95% CI	(6.5, 15.2)	(4.6, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.2009
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.786
		95% CI for Hazard Ratio			(0.542, 1.139)
	No	Number of Patients	20	20	
		Patients With Events (%)	6 (30.0)	7 (35.0)	
		Patients Without Events (Censored) (%)	14 (70.0)	13 (65.0)	
		Median Time (months) [a]	NE	NE	
		95% CI	(6.3, NE)	(1.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.2281
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.512
		95% CI for Hazard Ratio			(0.169, 1.553)
		P-value of Subgroup*Treatment Interaction [d]			0.2954

Note: "EQ-5D-5L Evaluable population" is defined as ITT subjects who completed at least one of the 5 dimensions or VAS score at baseline and at least one evaluable assessment at post-baseline visits based on EQ-5D-5L. A clinically meaningful worsening is defined as at least 15 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EQ-5D-5L = EuroQoL Five Dimensions, Five Levels questionnaire; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice; VAS = visual analog scale.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Anhang 4-G 6.4: Zeit bis zur Verschlechterung EORTC-QLQ-C30

Table 15.15.6.1
Summary of Time to First HRQoL Worsening for EORTC QLQ-C30 - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Patients With Events (%)	95 (54.9)	103 (62.8)	
	Patients Without Events (Censored) (%)	78 (45.1)	61 (37.2)	
	Median Time (months) [a]	4.9	2.6	
	95% CI	(3.0, 6.7)	(2.0, 3.5)	
	Log-rank p-value (Stratified) [b]			0.0041
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.663
	95% CI for Hazard Ratio			(0.499, 0.882)
Physical Functioning	Patients With Events (%)	88 (50.6)	87 (53.0)	
	Patients Without Events (Censored) (%)	86 (49.4)	77 (47.0)	
	Median Time (months) [a]	5.6	3.4	
	95% CI	(3.1, 8.3)	(2.2, 4.6)	
	Log-rank p-value (Stratified) [b]			0.0289
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.717
	95% CI for Hazard Ratio			(0.531, 0.970)
Role Functioning	Patients With Events (%)	111 (64.9)	102 (64.2)	
	Patients Without Events (Censored) (%)	60 (35.1)	57 (35.8)	
	Median Time (months) [a]	2.8	2.2	
	95% CI	(1.7, 4.3)	(1.5, 2.9)	
	Log-rank p-value (Stratified) [b]			0.0546
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.768
	95% CI for Hazard Ratio			(0.584, 1.010)
Emotional Functioning	Patients With Events (%)	61 (36.1)	75 (45.7)	
	Patients Without Events (Censored) (%)	108 (63.9)	89 (54.3)	
	Median Time (months) [a]	NE	4.5	
	95% CI	(6.5, NE)	(3.4, 9.5)	
	Log-rank p-value (Stratified) [b]			0.0117
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.647
	95% CI for Hazard Ratio			(0.459, 0.912)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.

[c] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.

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Table 15.15.6.1
Summary of Time to First HRQoL Worsening for EORTC QLQ-C30 - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Cognitive Functioning	Patients With Events (%)	86 (49.4)	67 (40.9)	
	Patients Without Events (Censored) (%)	88 (50.6)	97 (59.1)	
	Median Time (months) [a]	5.2	5.4	
	95% CI	(3.0, 11.1)	(3.3, NE)	
	Log-rank p-value (Stratified) [b]			0.9061
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			1.020
	95% CI for Hazard Ratio			(0.737, 1.411)
Social Functioning	Patients With Events (%)	101 (59.4)	88 (56.1)	
	Patients Without Events (Censored) (%)	69 (40.6)	69 (43.9)	
	Median Time (months) [a]	2.4	3.5	
	95% CI	(1.7, 4.3)	(2.6, 4.3)	
	Log-rank p-value (Stratified) [b]			0.9576
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.992
	95% CI for Hazard Ratio			(0.743, 1.325)
Fatigue	Patients With Events (%)	121 (70.3)	124 (76.5)	
	Patients Without Events (Censored) (%)	51 (29.7)	38 (23.5)	
	Median Time (months) [a]	2.1	1.3	
	95% CI	(1.6, 2.8)	(1.0, 1.8)	
	Log-rank p-value (Stratified) [b]			0.0019
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.672
	95% CI for Hazard Ratio			(0.519, 0.869)
Nausea and Vomiting	Patients With Events (%)	106 (61.3)	77 (46.7)	
	Patients Without Events (Censored) (%)	67 (38.7)	88 (53.3)	
	Median Time (months) [a]	2.4	4.6	
	95% CI	(1.6, 3.9)	(2.9, 9.5)	
	Log-rank p-value (Stratified) [b]			0.1273
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			1.256
	95% CI for Hazard Ratio			(0.933, 1.691)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.

[c] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.

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Table 15.15.6.1
Summary of Time to First HRQoL Worsening for EORTC QLQ-C30 - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Pain	Patients With Events (%)	95 (56.2)	90 (56.6)	
	Patients Without Events (Censored) (%)	74 (43.8)	69 (43.4)	
	Median Time (months) [a]	3.8	3.2	
	95% CI	(2.8, 6.1)	(2.2, 4.3)	
	Log-rank p-value (Stratified) [b]			0.2118
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.830
	95% CI for Hazard Ratio			(0.617, 1.116)
Dyspnea	Patients With Events (%)	78 (45.9)	84 (52.2)	
	Patients Without Events (Censored) (%)	92 (54.1)	77 (47.8)	
	Median Time (months) [a]	6.7	3.9	
	95% CI	(4.6, 9.5)	(2.4, 7.5)	
	Log-rank p-value (Stratified) [b]			0.0086
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.657
	95% CI for Hazard Ratio			(0.479, 0.903)
Insomnia	Patients With Events (%)	68 (42.5)	69 (46.0)	
	Patients Without Events (Censored) (%)	92 (57.5)	81 (54.0)	
	Median Time (months) [a]	8.7	3.6	
	95% CI	(6.0, 18.9)	(2.3, NE)	
	Log-rank p-value (Stratified) [b]			0.0212
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.672
	95% CI for Hazard Ratio			(0.476, 0.947)
Appetite Loss	Patients With Events (%)	97 (58.1)	78 (50.0)	
	Patients Without Events (Censored) (%)	70 (41.9)	78 (50.0)	
	Median Time (months) [a]	3.3	3.7	
	95% CI	(1.7, 5.9)	(2.3, 5.4)	
	Log-rank p-value (Stratified) [b]			0.6334
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			1.076
	95% CI for Hazard Ratio			(0.794, 1.457)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.

[c] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.

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Table 15.15.6.1
Summary of Time to First HRQoL Worsening for EORTC QLQ-C30 - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Patients With Events (%)	83 (48.8)	70 (44.3)	
	Patients Without Events (Censored) (%)	87 (51.2)	88 (55.7)	
	Median Time (months) [a]	5.4	4.8	
	95% CI	(3.2, 9.1)	(3.2, 8.2)	
	Log-rank p-value (Stratified) [b]			0.9420
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			1.012
	95% CI for Hazard Ratio			(0.734, 1.396)
Diarrhea	Patients With Events (%)	104 (60.5)	55 (33.5)	
	Patients Without Events (Censored) (%)	68 (39.5)	109 (66.5)	
	Median Time (months) [a]	2.0	8.2	
	95% CI	(1.6, 3.4)	(5.8, NE)	
	Log-rank p-value (Stratified) [b]			<.0001
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			2.408
	95% CI for Hazard Ratio			(1.721, 3.367)
Financial Difficulties	Patients With Events (%)	43 (25.4)	31 (19.5)	
	Patients Without Events (Censored) (%)	126 (74.6)	128 (80.5)	
	Median Time (months) [a]	NE	NE	
	95% CI	(18.2, NE)	(NE, NE)	
	Log-rank p-value (Stratified) [b]			0.5345
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			1.159
	95% CI for Hazard Ratio			(0.726, 1.850)
Summary Score	Patients With Events (%)	85 (48.9)	79 (47.9)	
	Patients Without Events (Censored) (%)	89 (51.1)	86 (52.1)	
	Median Time (months) [a]	5.6	4.9	
	95% CI	(3.7, 9.2)	(3.1, 8.2)	
	Log-rank p-value (Stratified) [b]			0.2647
	Stratified Cox Regression Analysis [c]			
	Hazard Ratio (Relative to TPC)			0.838
	95% CI for Hazard Ratio			(0.613, 1.146)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.

[c] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.

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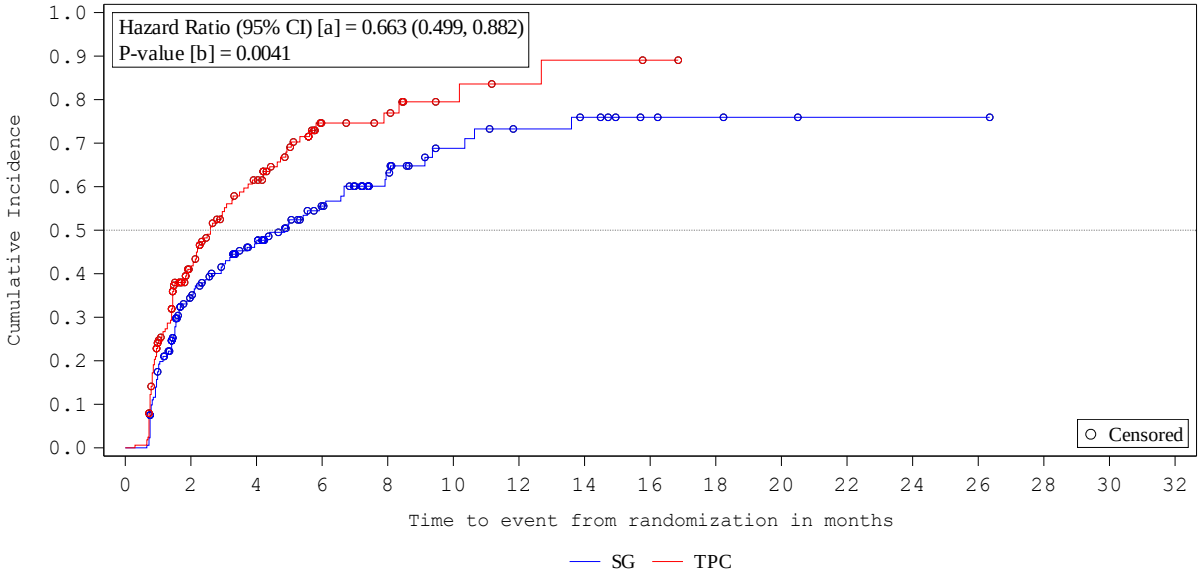
Figure 15.15.4.1.1
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Global Health Status/QoL by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**173**	**95**	**65**	**40**	**24**	**14**	**10**	**8**	**4**	**3**	**2**	**1**	**1**	**1**	**0**
TPC	**164**	**75**	**41**	**13**	**10**	**5**	**3**	**2**	**1**	**0**					

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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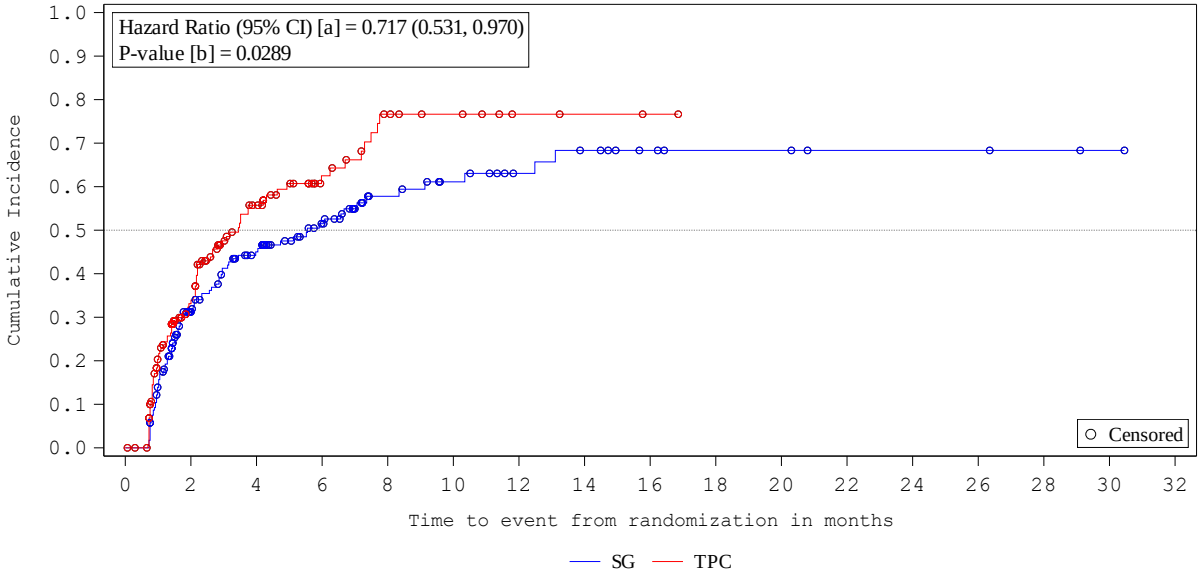
Figure 15.15.4.1.2
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Physical Functioning by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**174**	**100**	**69**	**46**	**26**	**20**	**14**	**11**	**7**	**5**	**5**	**3**	**3**	**3**	**2**	**1**	**0**
TPC	**164**	**83**	**41**	**21**	**10**	**7**	**3**	**2**	**1**	**0**							

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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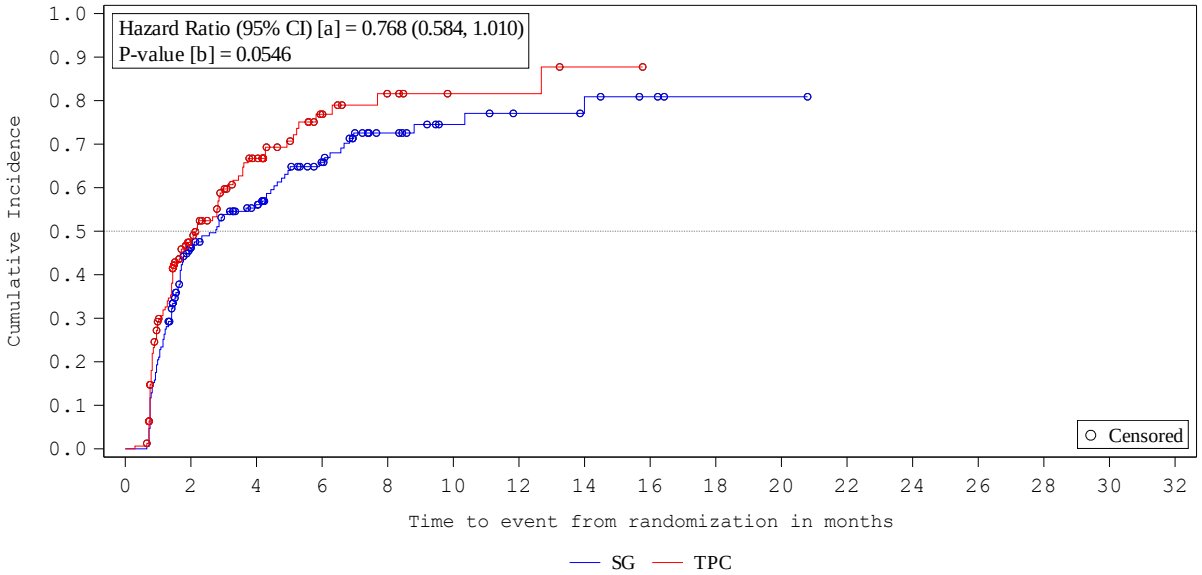
Figure 15.15.4.1.3
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Role Functioning by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	171	80	56	33	17	10	7	5	3	1	1	0
TPC	159	64	31	12	6	3	3	1	0			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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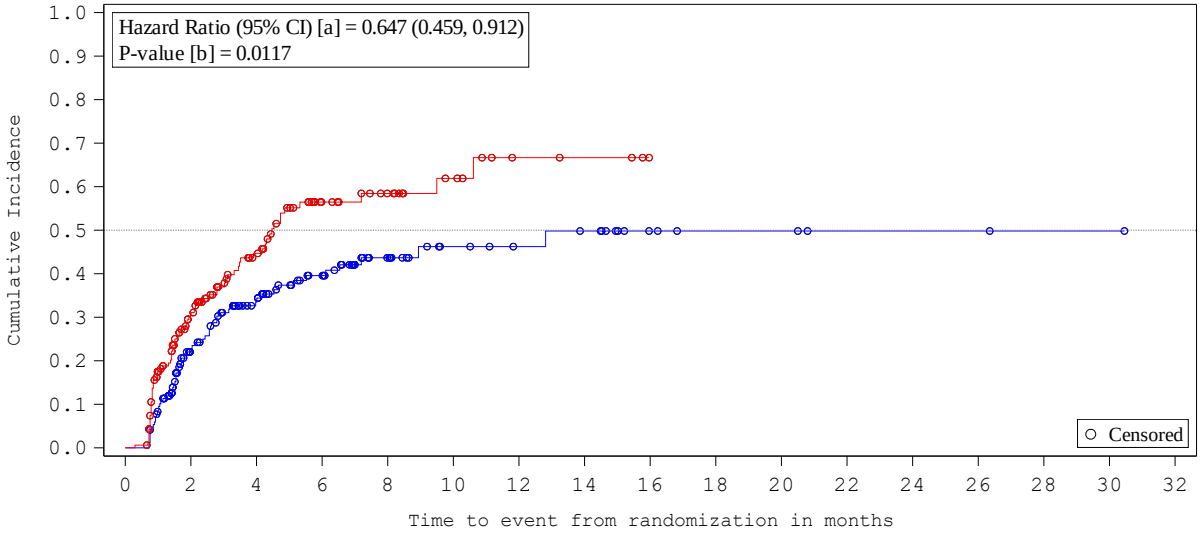
Figure 15.15.4.1.4
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Emotional Functioning by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**169**	**106**	**75**	**52**	**28**	**18**	**15**	**13**	**6**	**4**	**4**	**2**	**2**	**2**	**1**	**1**	**0**
TPC	**164**	**89**	**54**	**25**	**17**	**10**	**4**	**3**	**0**								

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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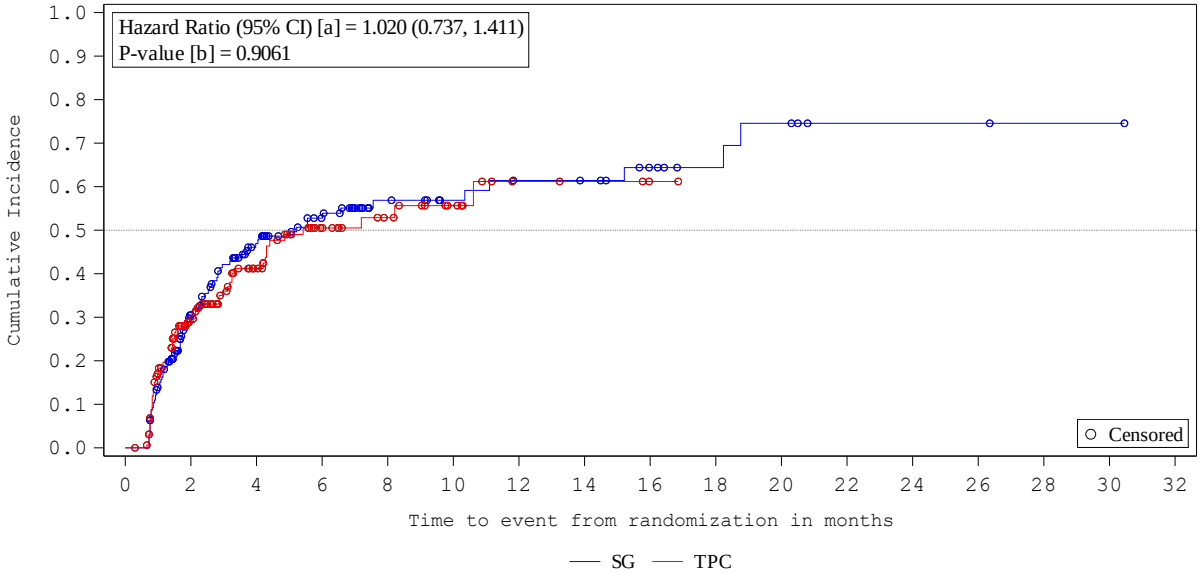
Figure 15.15.4.1.5
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Cognitive Functioning by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**174**	**99**	**62**	**42**	**24**	**19**	**16**	**15**	**10**	**7**	**5**	**2**	**2**	**2**	**1**	**1**	**0**
TPC	**164**	**86**	**49**	**26**	**18**	**11**	**4**	**3**	**1**	**0**							

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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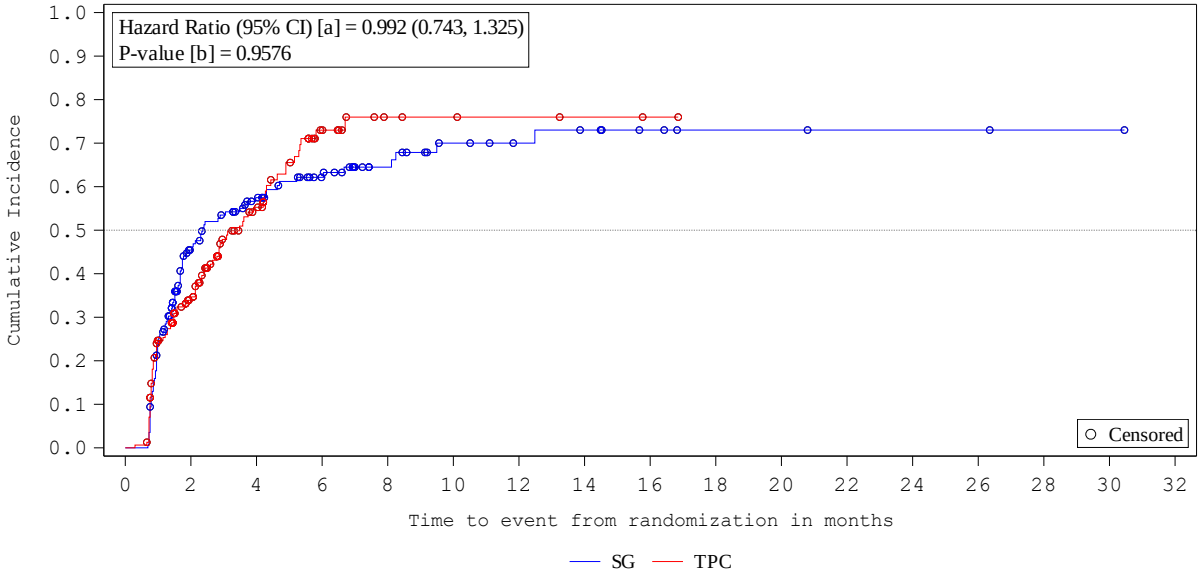
Figure 15.15.4.1.6
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Social Functioning by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	170	76	50	34	21	13	10	8	5	3	3	2	2	2	1	1	0
TPC	157	84	40	13	5	4	3	2	1	0							

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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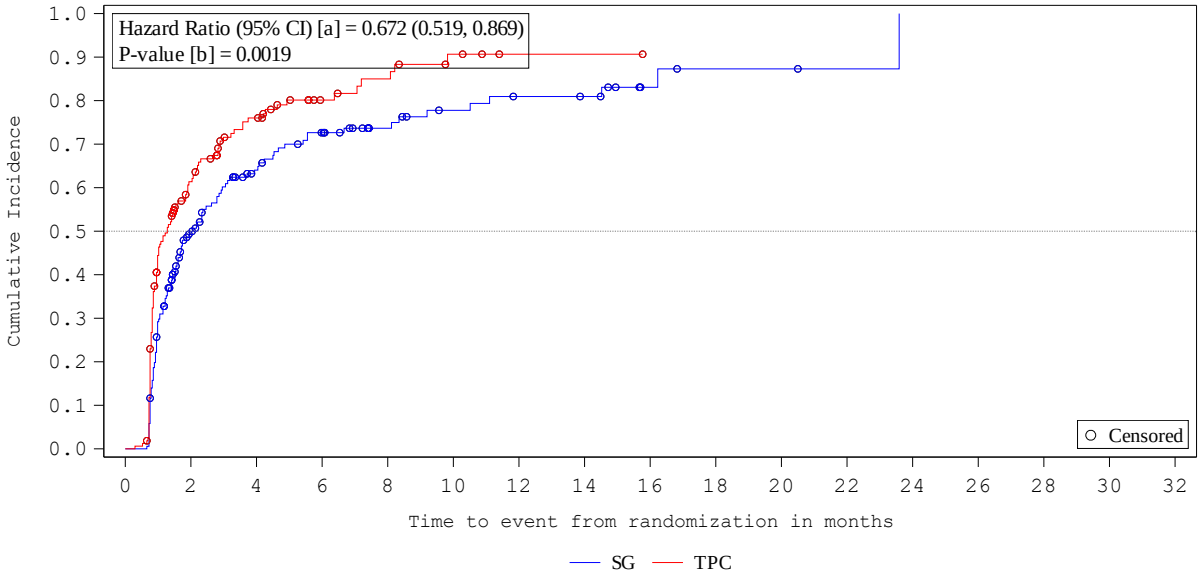
Figure 15.15.4.1.7
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Fatigue by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	172	72	43	30	20	14	11	10	4	2	2	1	0
TPC	162	52	27	13	9	4	1	1	0				

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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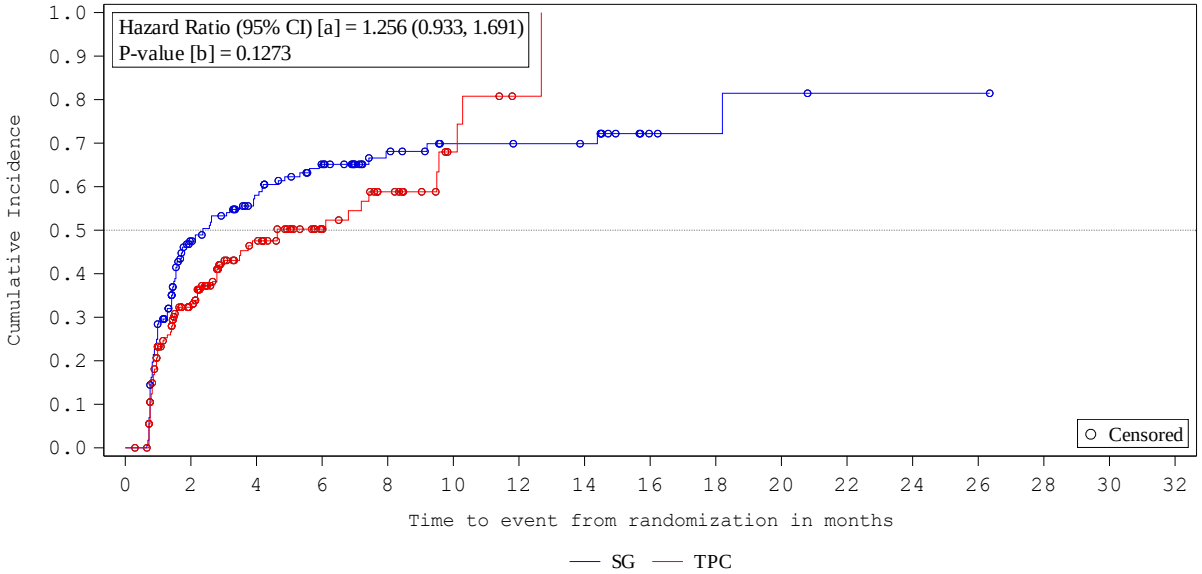
Figure 15.15.4.1.8
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Nausea and Vomiting by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	173	74	51	35	21	15	14	13	4	3	2	1	1	1	0
TPC	165	86	46	25	15	5	1	0							

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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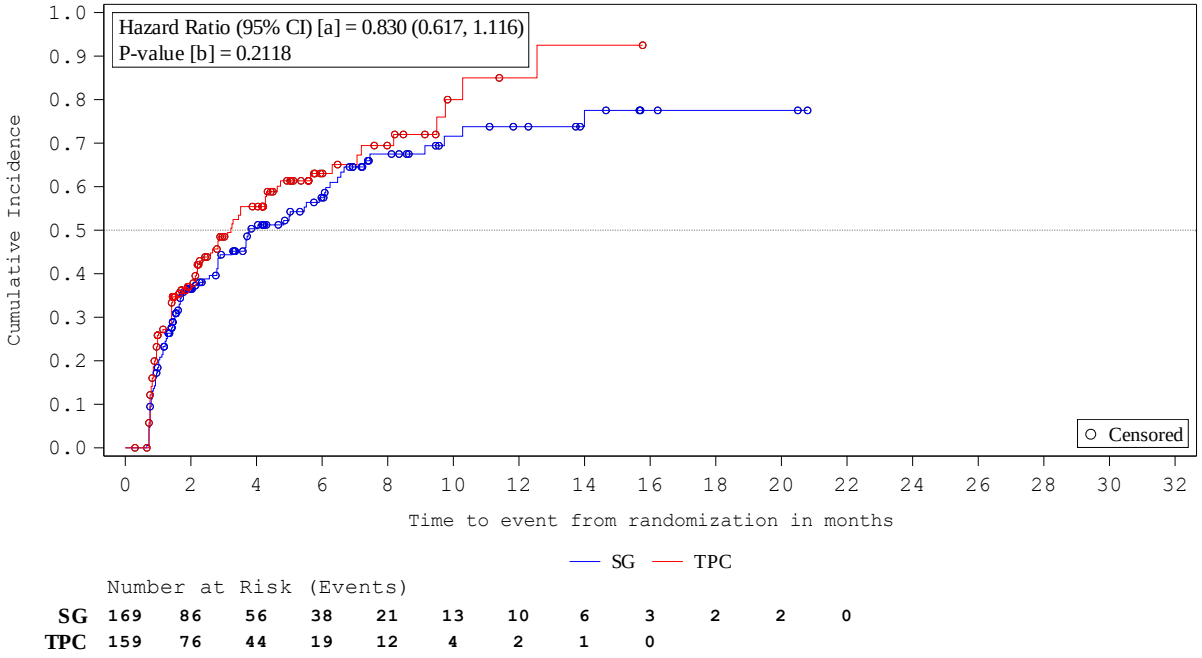
Figure 15.15.4.1.9
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Pain by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**169**	**86**	**56**	**38**	**21**	**13**	**10**	**6**	**3**	**2**	**2**	**0**
TPC	**159**	**76**	**44**	**19**	**12**	**4**	**2**	**1**	**0**			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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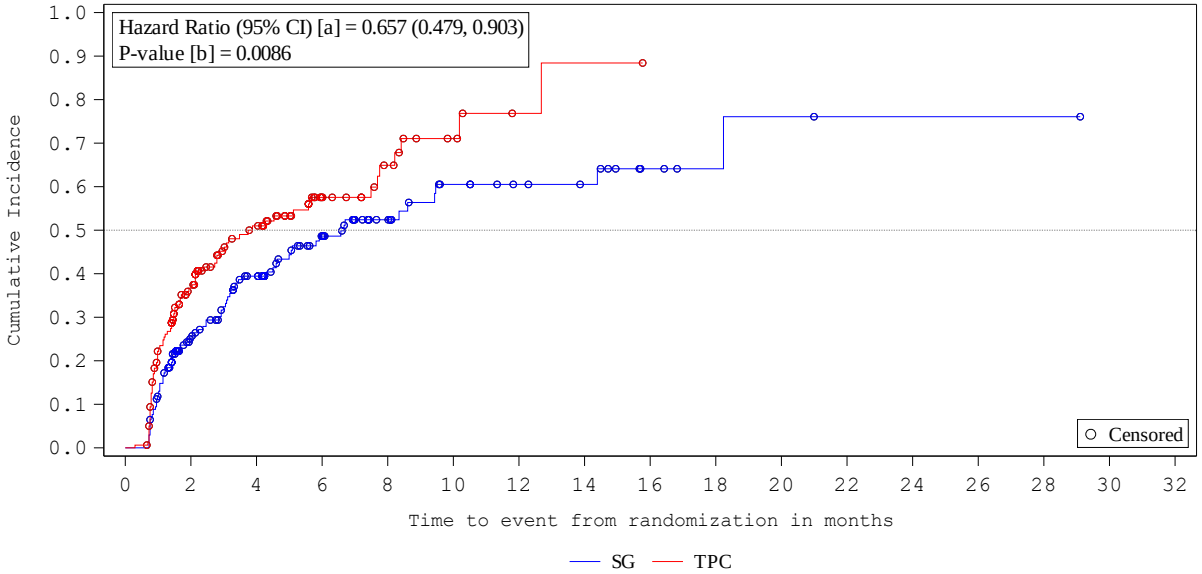
Figure 15.15.4.1.10
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Dyspnea by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	170	105	73	45	28	17	13	11	5	3	2	1	1	1	1	0
TPC	161	82	49	23	13	6	2	1	0							

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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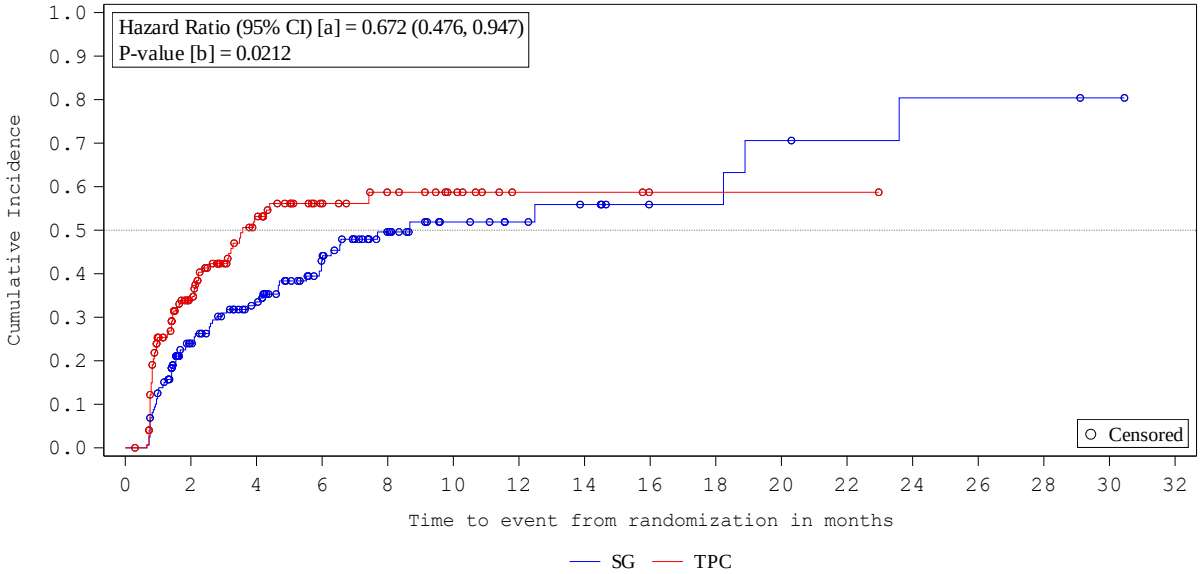
Figure 15.15.4.1.11
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Insomnia by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	160	101	76	48	29	17	13	10	6	6	4	3	2	2	2	1	0
TPC	150	75	37	20	14	9	3	3	1	1	1	1	0				

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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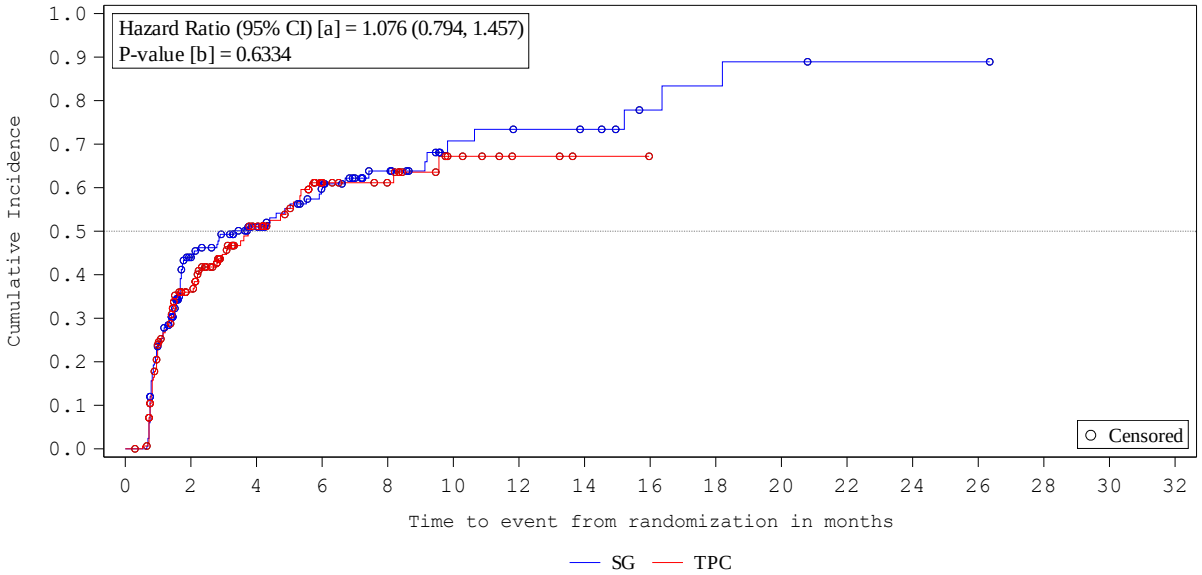
Figure 15.15.4.1.12
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Appetite Loss by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**167**	**77**	**55**	**34**	**21**	**11**	**9**	**8**	**4**	**3**	**2**	**1**	**1**	**1**	**0**
TPC	**156**	**80**	**42**	**21**	**16**	**7**	**3**	**1**	**0**						

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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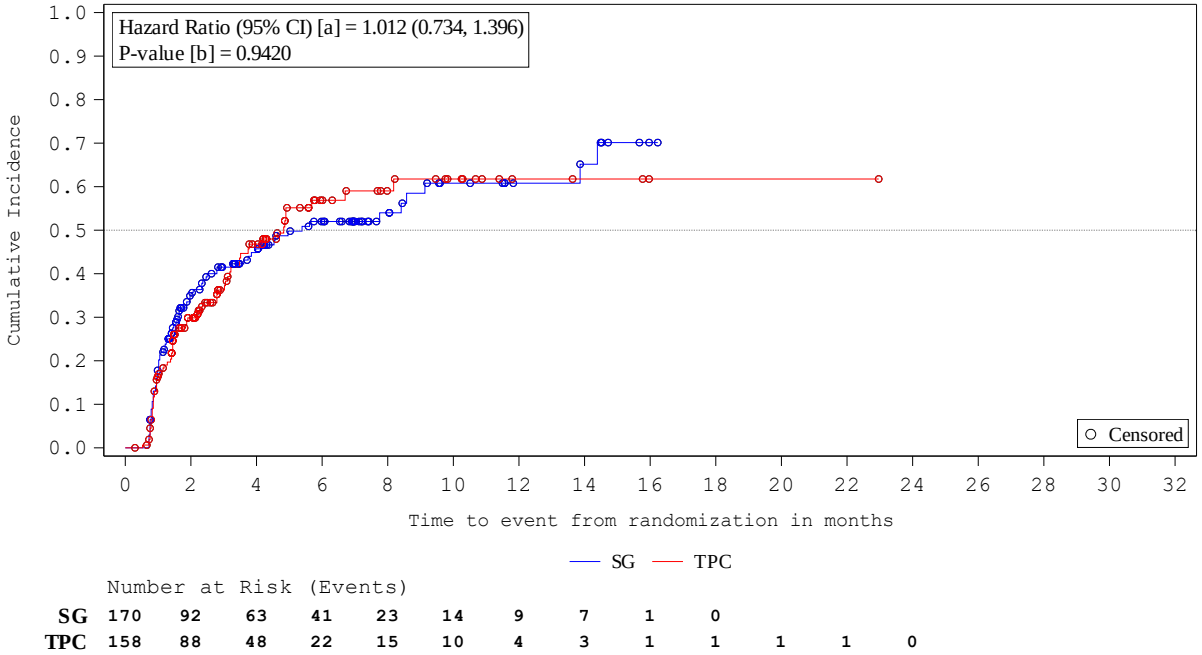
Figure 15.15.4.1.13
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Constipation by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**170**	**92**	**63**	**41**	**23**	**14**	**9**	**7**	**1**	**0**			
TPC	**158**	**88**	**48**	**22**	**15**	**10**	**4**	**3**	**1**	**1**	**1**	**1**	**0**

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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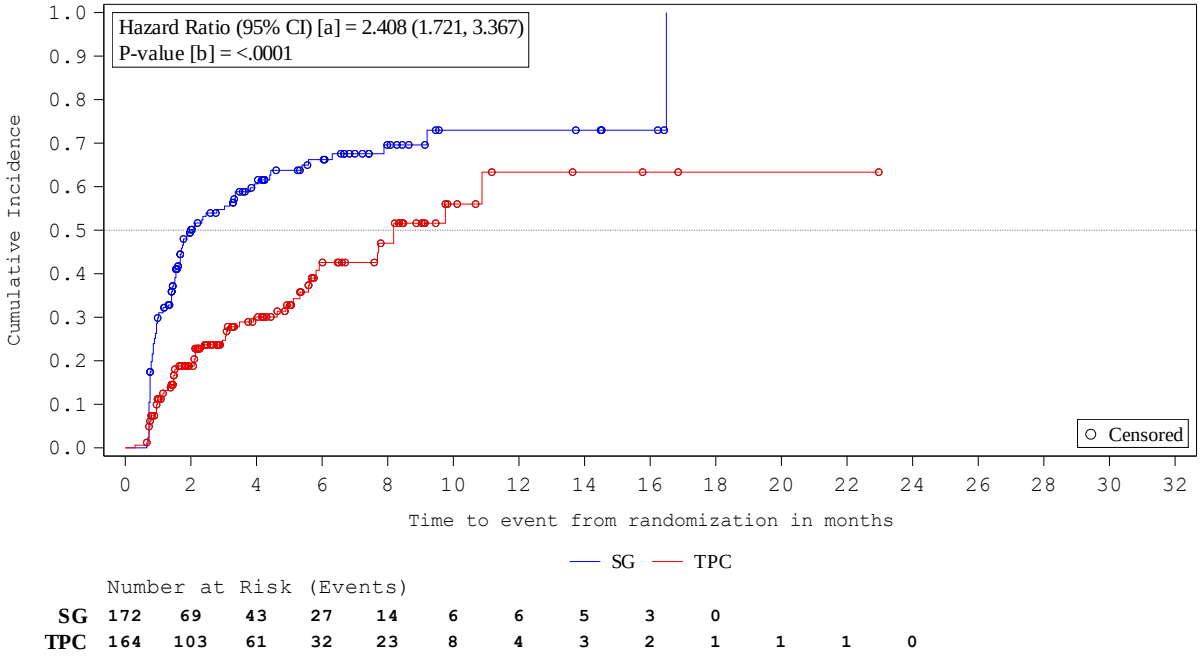
Figure 15.15.4.1.14
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Diarrhea by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	172	69	43	27	14	6	6	5	3	0			
TPC	164	103	61	32	23	8	4	3	2	1	1	1	0

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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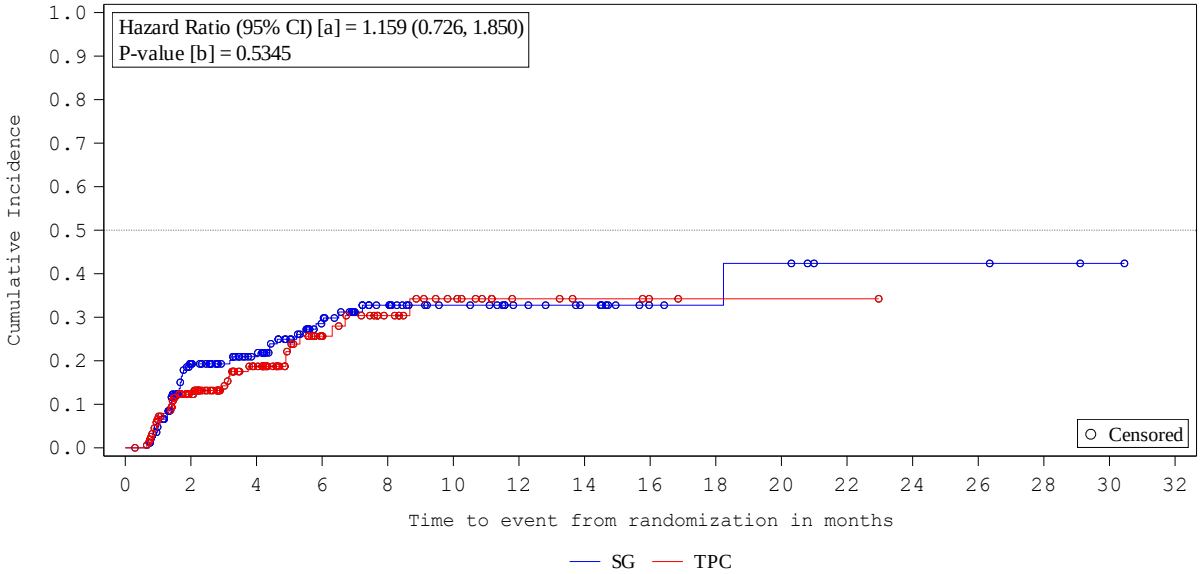
Figure 15.15.4.1.15
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Financial Difficulties by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**169**	**110**	**87**	**55**	**38**	**27**	**20**	**16**	**8**	**7**	**6**	**3**	**3**	**3**	**2**	**1**	**0**
TPC	**159**	**104**	**65**	**33**	**22**	**13**	**6**	**4**	**2**	**1**	**1**	**1**	**0**				

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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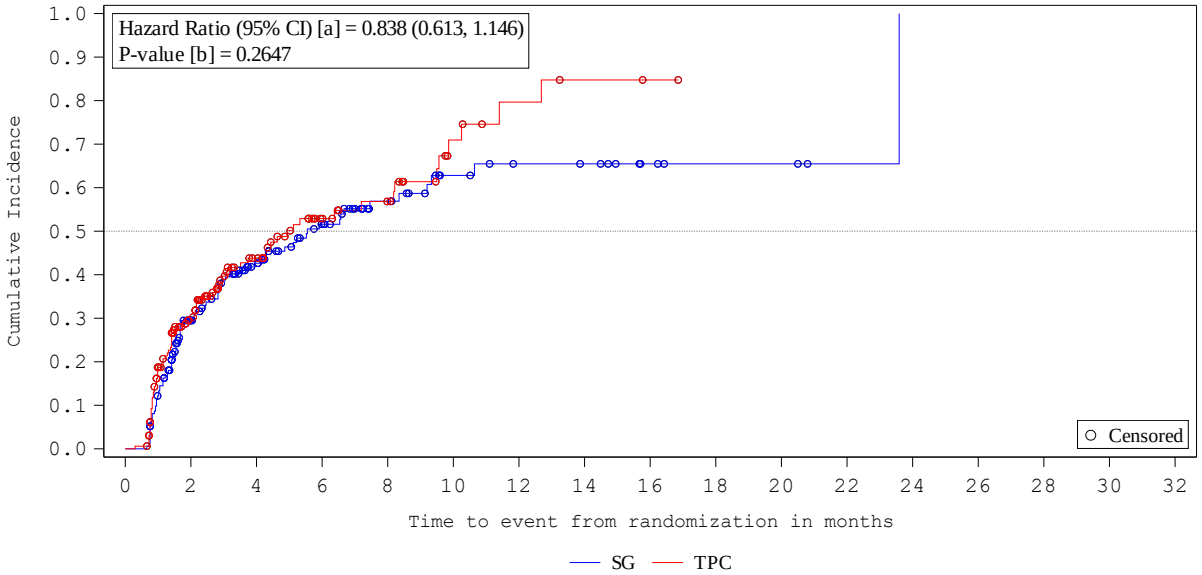
Figure 15.15.4.1.16
Kaplan-Meier Plot of Time to First Worsening in EORTC QLQ-C30 Summary Score by Treatment Group - Death Being Censored
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**174**	**103**	**68**	**44**	**25**	**15**	**11**	**10**	**5**	**3**	**3**	**1**	**0**
TPC	**165**	**92**	**51**	**27**	**20**	**8**	**4**	**2**	**1**	**0**			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.
[a] HR and 95% CI are estimated using a stratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate and the number of prior chemotherapy regimens for treatment of metastatic disease (two vs. three/four lines), visceral metastasis (Yes/No), and endocrine therapy in the metastatic setting for ≥6 months (Yes/No) as stratification factors in the model.
[b] P-value is estimated from stratified log-rank test stratified with randomization stratification factors.
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Anhang 4-G 6.4.1: Subgruppenanalysen

Gilead German Dossier IMMU-132-09 Data Cutoff Date: 01JUL2022

Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Two Lines	Number of Patients	78	82	
		Patients With Events (%)	45 (57.7)	49 (59.8)	
		Patients Without Events (Censored) (%)	33 (42.3)	33 (40.2)	
		Median Time (months) [a]	4.4	2.9	
		95% CI	(2.9, 8.0)	(2.0, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.2598
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.793
		95% CI for Hazard Ratio			(0.528, 1.191)
	Three/Four Lines	Number of Patients	95	82	
		Patients With Events (%)	50 (52.6)	54 (65.9)	
		Patients Without Events (Censored) (%)	45 (47.4)	28 (34.1)	
		Median Time (months) [a]	5.6	2.4	
		95% CI	(2.0, 9.1)	(1.4, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.0054
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.578
		95% CI for Hazard Ratio			(0.390, 0.857)
		P-value of Subgroup*Treatment Interaction [d]			0.2648
Physical Functioning	Two Lines	Number of Patients	78	83	
		Patients With Events (%)	38 (48.7)	41 (49.4)	
		Patients Without Events (Censored) (%)	40 (51.3)	42 (50.6)	
		Median Time (months) [a]	7.1	3.5	
		95% CI	(3.1, 13.1)	(2.2, 7.2)	
		Log-rank p-value (Unstratified) [b]			0.3237
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.801
		95% CI for Hazard Ratio			(0.514, 1.249)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Three/Four Lines	Number of Patients	96	81	
		Patients With Events (%)	50 (52.1)	46 (56.8)	
		Patients Without Events (Censored) (%)	46 (47.9)	35 (43.2)	
		Median Time (months) [a]	4.2	3.4	
		95% CI	(2.3, 7.4)	(1.9, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.0547
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.676
		95% CI for Hazard Ratio			(0.451, 1.014)
		P-value of Subgroup*Treatment Interaction [d]			0.5108
Role Functioning	Two Lines	Number of Patients	77	80	
		Patients With Events (%)	48 (62.3)	53 (66.3)	
		Patients Without Events (Censored) (%)	29 (37.7)	27 (33.8)	
		Median Time (months) [a]	4.2	2.7	
		95% CI	(1.7, 6.1)	(1.4, 3.6)	
		Log-rank p-value (Unstratified) [b]			0.1494
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.752
		95% CI for Hazard Ratio			(0.507, 1.114)
	Three/Four Lines	Number of Patients	94	79	
		Patients With Events (%)	63 (67.0)	49 (62.0)	
		Patients Without Events (Censored) (%)	31 (33.0)	30 (38.0)	
		Median Time (months) [a]	2.1	1.9	
		95% CI	(1.6, 4.0)	(1.4, 3.4)	
		Log-rank p-value (Unstratified) [b]			0.3379
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.834
		95% CI for Hazard Ratio			(0.571, 1.216)
		P-value of Subgroup*Treatment Interaction [d]			0.7410

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Two Lines	Number of Patients	75	82	
		Patients With Events (%)	24 (32.0)	36 (43.9)	
		Patients Without Events (Censored) (%)	51 (68.0)	46 (56.1)	
		Median Time (months) [a]	NE	7.2	
		95% CI	(8.9, NE)	(3.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0392
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.583
		95% CI for Hazard Ratio			(0.346, 0.982)
	Three/Four Lines	Number of Patients	94	82	
		Patients With Events (%)	37 (39.4)	39 (47.6)	
		Patients Without Events (Censored) (%)	57 (60.6)	43 (52.4)	
		Median Time (months) [a]	7.2	4.3	
		95% CI	(3.2, NE)	(3.0, 5.3)	
		Log-rank p-value (Unstratified) [b]			0.1007
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.688
		95% CI for Hazard Ratio			(0.438, 1.080)
		P-value of Subgroup*Treatment Interaction [d]			0.6115
Cognitive Functioning	Two Lines	Number of Patients	78	83	
		Patients With Events (%)	38 (48.7)	31 (37.3)	
		Patients Without Events (Censored) (%)	40 (51.3)	52 (62.7)	
		Median Time (months) [a]	5.6	10.6	
		95% CI	(2.8, NE)	(4.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.3834
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.233
		95% CI for Hazard Ratio			(0.767, 1.984)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Three/Four Lines	Number of Patients	96	81	
		Patients With Events (%)	48 (50.0)	36 (44.4)	
		Patients Without Events (Censored) (%)	48 (50.0)	45 (55.6)	
		Median Time (months) [a]	4.1	4.3	
		95% CI	(2.6, 11.1)	(2.9, 5.4)	
		Log-rank p-value (Unstratified) [b]			0.5360
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.871
		95% CI for Hazard Ratio			(0.561, 1.352)
		P-value of Subgroup*Treatment Interaction [d]			0.3568
Social Functioning	Two Lines	Number of Patients	77	81	
		Patients With Events (%)	45 (58.4)	46 (56.8)	
		Patients Without Events (Censored) (%)	32 (41.6)	35 (43.2)	
		Median Time (months) [a]	3.7	3.0	
		95% CI	(1.7, 8.2)	(2.2, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.6523
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.910
		95% CI for Hazard Ratio			(0.601, 1.377)
	Three/Four Lines	Number of Patients	93	76	
		Patients With Events (%)	56 (60.2)	42 (55.3)	
		Patients Without Events (Censored) (%)	37 (39.8)	34 (44.7)	
		Median Time (months) [a]	2.0	4.3	
		95% CI	(1.7, 3.6)	(2.4, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.7735
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.060
		95% CI for Hazard Ratio			(0.709, 1.583)
		P-value of Subgroup*Treatment Interaction [d]			0.6738

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Two Lines	Number of Patients	78	83	
		Patients With Events (%)	53 (67.9)	62 (74.7)	
		Patients Without Events (Censored) (%)	25 (32.1)	21 (25.3)	
		Median Time (months) [a]	2.9	1.4	
		95% CI	(1.7, 4.1)	(1.0, 2.1)	
		Log-rank p-value (Unstratified) [b]			0.0225
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.654
		95% CI for Hazard Ratio			(0.451, 0.950)
	Three/Four Lines	Number of Patients	94	79	
		Patients With Events (%)	68 (72.3)	62 (78.5)	
		Patients Without Events (Censored) (%)	26 (27.7)	17 (21.5)	
		Median Time (months) [a]	1.6	1.1	
		95% CI	(1.3, 2.2)	(0.9, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0592
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.720
		95% CI for Hazard Ratio			(0.508, 1.021)
		P-value of Subgroup*Treatment Interaction [d]			0.7550
Nausea and Vomiting	Two Lines	Number of Patients	77	83	
		Patients With Events (%)	47 (61.0)	40 (48.2)	
		Patients Without Events (Censored) (%)	30 (39.0)	43 (51.8)	
		Median Time (months) [a]	3.2	7.2	
		95% CI	(1.5, 5.9)	(2.7, 10.3)	
		Log-rank p-value (Unstratified) [b]			0.4538
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.174
		95% CI for Hazard Ratio			(0.767, 1.797)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Three/Four Lines	Number of Patients	96	82	
		Patients With Events (%)	59 (61.5)	37 (45.1)	
		Patients Without Events (Censored) (%)	37 (38.5)	45 (54.9)	
		Median Time (months) [a]	1.9	3.9	
		95% CI	(1.4, 3.9)	(2.8, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.1389
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.360
		95% CI for Hazard Ratio			(0.899, 2.057)
		P-value of Subgroup*Treatment Interaction [d]			0.7490
Pain	Two Lines	Number of Patients	75	83	
		Patients With Events (%)	47 (62.7)	51 (61.4)	
		Patients Without Events (Censored) (%)	28 (37.3)	32 (38.6)	
		Median Time (months) [a]	3.7	3.2	
		95% CI	(2.3, 6.2)	(1.9, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.4668
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.864
		95% CI for Hazard Ratio			(0.580, 1.286)
	Three/Four Lines	Number of Patients	94	76	
		Patients With Events (%)	48 (51.1)	39 (51.3)	
		Patients Without Events (Censored) (%)	46 (48.9)	37 (48.7)	
		Median Time (months) [a]	3.8	3.3	
		95% CI	(2.6, 6.6)	(2.1, 7.1)	
		Log-rank p-value (Unstratified) [b]			0.3417
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.815
		95% CI for Hazard Ratio			(0.531, 1.249)
		P-value of Subgroup*Treatment Interaction [d]			0.7771

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Two Lines	Number of Patients	75	83	
		Patients With Events (%)	34 (45.3)	42 (50.6)	
		Patients Without Events (Censored) (%)	41 (54.7)	41 (49.4)	
		Median Time (months) [a]	8.3	5.6	
		95% CI	(3.1, NE)	(2.2, 10.2)	
		Log-rank p-value (Unstratified) [b]			0.2488
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.768
		95% CI for Hazard Ratio			(0.488, 1.208)
	Three/Four Lines	Number of Patients	95	78	
		Patients With Events (%)	44 (46.3)	42 (53.8)	
		Patients Without Events (Censored) (%)	51 (53.7)	36 (46.2)	
		Median Time (months) [a]	6.6	3.0	
		95% CI	(4.3, 14.4)	(1.9, 5.1)	
		Log-rank p-value (Unstratified) [b]			0.0154
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.588
		95% CI for Hazard Ratio			(0.381, 0.910)
		P-value of Subgroup*Treatment Interaction [d]			0.4504
Insomnia	Two Lines	Number of Patients	72	77	
		Patients With Events (%)	29 (40.3)	38 (49.4)	
		Patients Without Events (Censored) (%)	43 (59.7)	39 (50.6)	
		Median Time (months) [a]	12.5	3.6	
		95% CI	(6.3, 23.6)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0399
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.604
		95% CI for Hazard Ratio			(0.369, 0.987)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Three/Four Lines	Number of Patients	88	73	
		Patients With Events (%)	39 (44.3)	31 (42.5)	
		Patients Without Events (Censored) (%)	49 (55.7)	42 (57.5)	
		Median Time (months) [a]	6.0	3.5	
		95% CI	(3.7, NE)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.2059
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.736
		95% CI for Hazard Ratio			(0.455, 1.190)
		P-value of Subgroup*Treatment Interaction [d]			0.5671
Appetite Loss	Two Lines	Number of Patients	77	80	
		Patients With Events (%)	43 (55.8)	38 (47.5)	
		Patients Without Events (Censored) (%)	34 (44.2)	42 (52.5)	
		Median Time (months) [a]	4.4	4.4	
		95% CI	(2.1, 9.8)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.7400
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.077
		95% CI for Hazard Ratio			(0.692, 1.676)
	Three/Four Lines	Number of Patients	90	76	
		Patients With Events (%)	54 (60.0)	40 (52.6)	
		Patients Without Events (Censored) (%)	36 (40.0)	36 (47.4)	
		Median Time (months) [a]	2.8	3.7	
		95% CI	(1.7, 5.9)	(1.5, 5.4)	
		Log-rank p-value (Unstratified) [b]			0.8670
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.035
		95% CI for Hazard Ratio			(0.686, 1.562)
		P-value of Subgroup*Treatment Interaction [d]			0.8766

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Two Lines	Number of Patients	77	82	
		Patients With Events (%)	35 (45.5)	36 (43.9)	
		Patients Without Events (Censored) (%)	42 (54.5)	46 (56.1)	
		Median Time (months) [a]	8.4	5.7	
		95% CI	(3.2, NE)	(3.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.9082
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.973
		95% CI for Hazard Ratio			(0.611, 1.551)
	Three/Four Lines	Number of Patients	93	76	
		Patients With Events (%)	48 (51.6)	34 (44.7)	
		Patients Without Events (Censored) (%)	45 (48.4)	42 (55.3)	
		Median Time (months) [a]	4.5	3.5	
		95% CI	(2.0, 14.4)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.8804
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.034
		95% CI for Hazard Ratio			(0.664, 1.610)
		P-value of Subgroup*Treatment Interaction [d]			0.8993
Diarrhea	Two Lines	Number of Patients	77	82	
		Patients With Events (%)	42 (54.5)	30 (36.6)	
		Patients Without Events (Censored) (%)	35 (45.5)	52 (63.4)	
		Median Time (months) [a]	3.2	7.7	
		95% CI	(1.8, 16.5)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.0248
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.696
		95% CI for Hazard Ratio			(1.061, 2.711)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Three/Four Lines	Number of Patients	95	82	
		Patients With Events (%)	62 (65.3)	25 (30.5)	
		Patients Without Events (Censored) (%)	33 (34.7)	57 (69.5)	
		Median Time (months) [a]	1.6	9.8	
		95% CI	(1.4, 3.0)	(5.3, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			3.018
		95% CI for Hazard Ratio			(1.889, 4.823)
		P-value of Subgroup*Treatment Interaction [d]			0.1036
Financial Difficulties	Two Lines	Number of Patients	77	81	
		Patients With Events (%)	25 (32.5)	17 (21.0)	
		Patients Without Events (Censored) (%)	52 (67.5)	64 (79.0)	
		Median Time (months) [a]	NE	NE	
		95% CI	(6.0, NE)	(8.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.2975
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.385
		95% CI for Hazard Ratio			(0.747, 2.567)
	Three/Four Lines	Number of Patients	92	78	
		Patients With Events (%)	18 (19.6)	14 (17.9)	
		Patients Without Events (Censored) (%)	74 (80.4)	64 (82.1)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.7399
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.887
		95% CI for Hazard Ratio			(0.436, 1.805)
		P-value of Subgroup*Treatment Interaction [d]			0.3495

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.1
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Number of Prior Chemotherapy Regimens in Metastatic Setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Two Lines	Number of Patients	78	83	
		Patients With Events (%)	37 (47.4)	40 (48.2)	
		Patients Without Events (Censored) (%)	41 (52.6)	43 (51.8)	
		Median Time (months) [a]	6.5	7.2	
		95% CI	(4.2, 23.6)	(3.0, 11.4)	
		Log-rank p-value (Unstratified) [b]			0.5161
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.862
		95% CI for Hazard Ratio			(0.549, 1.353)
	Three/Four Lines	Number of Patients	96	82	
		Patients With Events (%)	48 (50.0)	39 (47.6)	
		Patients Without Events (Censored) (%)	48 (50.0)	43 (52.4)	
		Median Time (months) [a]	4.9	4.4	
		95% CI	(2.8, 9.3)	(2.8, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.4053
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.835
		95% CI for Hazard Ratio			(0.544, 1.281)
		P-value of Subgroup*Treatment Interaction [d]			0.9004

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Yes	Number of Patients	165	157	
		Patients With Events (%)	92 (55.8)	99 (63.1)	
		Patients Without Events (Censored) (%)	73 (44.2)	58 (36.9)	
		Median Time (months) [a]	4.4	2.6	
		95% CI	(2.9, 6.6)	(1.9, 3.5)	
		Log-rank p-value (Unstratified) [b]			0.0065
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.675
		95% CI for Hazard Ratio			(0.506, 0.899)
	No	Number of Patients	8	7	
		Patients With Events (%)	3 (37.5)	4 (57.1)	
		Patients Without Events (Censored) (%)	5 (62.5)	3 (42.9)	
		Median Time (months) [a]	NE	2.6	
		95% CI	(0.8, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.4726
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.584
		95% CI for Hazard Ratio			(0.130, 2.621)
		P-value of Subgroup*Treatment Interaction [d]			0.8406
Physical Functioning	Yes	Number of Patients	166	157	
		Patients With Events (%)	86 (51.8)	84 (53.5)	
		Patients Without Events (Censored) (%)	80 (48.2)	73 (46.5)	
		Median Time (months) [a]	5.1	3.4	
		95% CI	(3.0, 8.3)	(2.2, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.0812
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.765
		95% CI for Hazard Ratio			(0.565, 1.036)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	8	7	
		Patients With Events (%)	2 (25.0)	3 (42.9)	
		Patients Without Events (Censored) (%)	6 (75.0)	4 (57.1)	
		Median Time (months) [a]	NE	3.5	
		95% CI	(1.6, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.1637
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.294
		95% CI for Hazard Ratio			(0.048, 1.817)
		P-value of Subgroup*Treatment Interaction [d]			0.4436
Role Functioning	Yes	Number of Patients	163	152	
		Patients With Events (%)	106 (65.0)	97 (63.8)	
		Patients Without Events (Censored) (%)	57 (35.0)	55 (36.2)	
		Median Time (months) [a]	2.6	2.2	
		95% CI	(1.7, 4.2)	(1.5, 3.0)	
		Log-rank p-value (Unstratified) [b]			0.1218
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.805
		95% CI for Hazard Ratio			(0.610, 1.063)
	No	Number of Patients	8	7	
		Patients With Events (%)	5 (62.5)	5 (71.4)	
		Patients Without Events (Censored) (%)	3 (37.5)	2 (28.6)	
		Median Time (months) [a]	4.9	1.4	
		95% CI	(0.8, 7.0)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.4977
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.659
		95% CI for Hazard Ratio			(0.187, 2.319)
		P-value of Subgroup*Treatment Interaction [d]			0.6409

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Yes	Number of Patients	161	157	
		Patients With Events (%)	58 (36.0)	73 (46.5)	
		Patients Without Events (Censored) (%)	103 (64.0)	84 (53.5)	
		Median Time (months) [a]	NE	4.5	
		95% CI	(6.1, NE)	(3.3, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.0069
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.624
		95% CI for Hazard Ratio			(0.442, 0.883)
	No	Number of Patients	8	7	
		Patients With Events (%)	3 (37.5)	2 (28.6)	
		Patients Without Events (Censored) (%)	5 (62.5)	5 (71.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(0.8, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.7731
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.296
		95% CI for Hazard Ratio			(0.216, 7.767)
		P-value of Subgroup*Treatment Interaction [d]			0.3873
Cognitive Functioning	Yes	Number of Patients	166	157	
		Patients With Events (%)	82 (49.4)	63 (40.1)	
		Patients Without Events (Censored) (%)	84 (50.6)	94 (59.9)	
		Median Time (months) [a]	5.2	5.4	
		95% CI	(3.0, 10.3)	(4.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.7483
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.055
		95% CI for Hazard Ratio			(0.758, 1.470)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	8	7	
		Patients With Events (%)	4 (50.0)	4 (57.1)	
		Patients Without Events (Censored) (%)	4 (50.0)	3 (42.9)	
		Median Time (months) [a]	NE	2.3	
		95% CI	(0.8, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.7322
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.789
		95% CI for Hazard Ratio			(0.197, 3.162)
		P-value of Subgroup*Treatment Interaction [d]			0.6968
Social Functioning	Yes	Number of Patients	162	150	
		Patients With Events (%)	99 (61.1)	84 (56.0)	
		Patients Without Events (Censored) (%)	63 (38.9)	66 (44.0)	
		Median Time (months) [a]	2.3	3.5	
		95% CI	(1.7, 3.7)	(2.4, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.8521
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.028
		95% CI for Hazard Ratio			(0.767, 1.378)
	No	Number of Patients	8	7	
		Patients With Events (%)	2 (25.0)	4 (57.1)	
		Patients Without Events (Censored) (%)	6 (75.0)	3 (42.9)	
		Median Time (months) [a]	NE	2.6	
		95% CI	(0.8, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.1731
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.337
		95% CI for Hazard Ratio			(0.061, 1.862)
		P-value of Subgroup*Treatment Interaction [d]			0.1356

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Yes	Number of Patients	164	155	
		Patients With Events (%)	115 (70.1)	118 (76.1)	
		Patients Without Events (Censored) (%)	49 (29.9)	37 (23.9)	
		Median Time (months) [a]	2.1	1.3	
		95% CI	(1.6, 2.9)	(1.0, 1.8)	
		Log-rank p-value (Unstratified) [b]			0.0042
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.689
		95% CI for Hazard Ratio			(0.531, 0.894)
	No	Number of Patients	8	7	
		Patients With Events (%)	6 (75.0)	6 (85.7)	
		Patients Without Events (Censored) (%)	2 (25.0)	1 (14.3)	
		Median Time (months) [a]	1.5	0.8	
		95% CI	(0.7, NE)	(0.7, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.3531
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.606
		95% CI for Hazard Ratio			(0.193, 1.903)
		P-value of Subgroup*Treatment Interaction [d]			0.7655
Nausea and Vomiting	Yes	Number of Patients	165	158	
		Patients With Events (%)	102 (61.8)	73 (46.2)	
		Patients Without Events (Censored) (%)	63 (38.2)	85 (53.8)	
		Median Time (months) [a]	2.4	6.1	
		95% CI	(1.6, 3.9)	(2.9, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.0997
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.285
		95% CI for Hazard Ratio			(0.949, 1.740)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	8	7	
		Patients With Events (%)	4 (50.0)	4 (57.1)	
		Patients Without Events (Censored) (%)	4 (50.0)	3 (42.9)	
		Median Time (months) [a]	2.6	3.5	
		95% CI	(0.8, NE)	(0.8, 3.5)	
		Log-rank p-value (Unstratified) [b]			0.6554
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.725
		95% CI for Hazard Ratio			(0.173, 3.038)
		P-value of Subgroup*Treatment Interaction [d]			0.4437
Pain	Yes	Number of Patients	162	152	
		Patients With Events (%)	90 (55.6)	87 (57.2)	
		Patients Without Events (Censored) (%)	72 (44.4)	65 (42.8)	
		Median Time (months) [a]	4.0	3.1	
		95% CI	(2.8, 6.1)	(2.2, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.0998
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.781
		95% CI for Hazard Ratio			(0.580, 1.052)
	No	Number of Patients	7	7	
		Patients With Events (%)	5 (71.4)	3 (42.9)	
		Patients Without Events (Censored) (%)	2 (28.6)	4 (57.1)	
		Median Time (months) [a]	1.1	8.2	
		95% CI	(0.7, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.1165
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			3.295
		95% CI for Hazard Ratio			(0.636, 17.061)
		P-value of Subgroup*Treatment Interaction [d]			0.0540

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Yes	Number of Patients	162	154	
		Patients With Events (%)	75 (46.3)	82 (53.2)	
		Patients Without Events (Censored) (%)	87 (53.7)	72 (46.8)	
		Median Time (months) [a]	6.6	3.7	
		95% CI	(4.5, 9.5)	(2.4, 7.5)	
		Log-rank p-value (Unstratified) [b]			0.0081
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.654
		95% CI for Hazard Ratio			(0.476, 0.899)
	No	Number of Patients	8	7	
		Patients With Events (%)	3 (37.5)	2 (28.6)	
		Patients Without Events (Censored) (%)	5 (62.5)	5 (71.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(0.8, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.7910
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.257
		95% CI for Hazard Ratio			(0.210, 7.530)
		P-value of Subgroup*Treatment Interaction [d]			0.4005
Insomnia	Yes	Number of Patients	153	143	
		Patients With Events (%)	66 (43.1)	65 (45.5)	
		Patients Without Events (Censored) (%)	87 (56.9)	78 (54.5)	
		Median Time (months) [a]	7.7	3.9	
		95% CI	(5.9, 18.9)	(2.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.0333
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.689
		95% CI for Hazard Ratio			(0.487, 0.976)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	7	7	
		Patients With Events (%)	2 (28.6)	4 (57.1)	
		Patients Without Events (Censored) (%)	5 (71.4)	3 (42.9)	
		Median Time (months) [a]	NE	2.6	
		95% CI	(1.1, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.2739
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.402
		95% CI for Hazard Ratio			(0.073, 2.222)
		P-value of Subgroup*Treatment Interaction [d]			0.4293
Appetite Loss	Yes	Number of Patients	159	150	
		Patients With Events (%)	93 (58.5)	73 (48.7)	
		Patients Without Events (Censored) (%)	66 (41.5)	77 (51.3)	
		Median Time (months) [a]	3.3	4.4	
		95% CI	(1.7, 5.9)	(2.2, 5.6)	
		Log-rank p-value (Unstratified) [b]			0.5553
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.096
		95% CI for Hazard Ratio			(0.805, 1.493)
	No	Number of Patients	8	6	
		Patients With Events (%)	4 (50.0)	5 (83.3)	
		Patients Without Events (Censored) (%)	4 (50.0)	1 (16.7)	
		Median Time (months) [a]	NE	3.5	
		95% CI	(0.7, NE)	(0.8, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.6937
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.767
		95% CI for Hazard Ratio			(0.191, 3.083)
		P-value of Subgroup*Treatment Interaction [d]			0.4487

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Yes	Number of Patients	162	151	
		Patients With Events (%)	80 (49.4)	68 (45.0)	
		Patients Without Events (Censored) (%)	82 (50.6)	83 (55.0)	
		Median Time (months) [a]	5.0	4.8	
		95% CI	(3.2, 9.1)	(3.2, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.8607
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.029
		95% CI for Hazard Ratio			(0.744, 1.424)
	No	Number of Patients	8	7	
		Patients With Events (%)	3 (37.5)	2 (28.6)	
		Patients Without Events (Censored) (%)	5 (62.5)	5 (71.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(1.6, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.9870
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.985
		95% CI for Hazard Ratio			(0.162, 6.002)
		P-value of Subgroup*Treatment Interaction [d]			0.9586
Diarrhea	Yes	Number of Patients	164	157	
		Patients With Events (%)	99 (60.4)	53 (33.8)	
		Patients Without Events (Censored) (%)	65 (39.6)	104 (66.2)	
		Median Time (months) [a]	2.1	8.2	
		95% CI	(1.7, 3.4)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.217
		95% CI for Hazard Ratio			(1.586, 3.097)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	8	7	
		Patients With Events (%)	5 (62.5)	2 (28.6)	
		Patients Without Events (Censored) (%)	3 (37.5)	5 (71.4)	
		Median Time (months) [a]	1.3	8.2	
		95% CI	(0.7, NE)	(1.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0579
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			5.968
		95% CI for Hazard Ratio			(0.693, 51.429)
		P-value of Subgroup*Treatment Interaction [d]			0.4559
Financial Difficulties	Yes	Number of Patients	161	152	
		Patients With Events (%)	43 (26.7)	29 (19.1)	
		Patients Without Events (Censored) (%)	118 (73.3)	123 (80.9)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.4178
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.215
		95% CI for Hazard Ratio			(0.757, 1.950)
	No	Number of Patients	8	7	
		Patients With Events (%)	0 (0.0)	2 (28.6)	
		Patients Without Events (Censored) (%)	8 (100.0)	5 (71.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(NE, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.1286
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			<0.001
		95% CI for Hazard Ratio			(<0.001, NE)
		P-value of Subgroup*Treatment Interaction [d]			0.9847

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.2
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Visceral metastasis
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Yes	Number of Patients	166	158	
		Patients With Events (%)	80 (48.2)	76 (48.1)	
		Patients Without Events (Censored) (%)	86 (51.8)	82 (51.9)	
		Median Time (months) [a]	5.9	4.9	
		95% CI	(3.9, 9.2)	(3.1, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.2361
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.827
		95% CI for Hazard Ratio			(0.603, 1.135)
	No	Number of Patients	8	7	
		Patients With Events (%)	5 (62.5)	3 (42.9)	
		Patients Without Events (Censored) (%)	3 (37.5)	4 (57.1)	
		Median Time (months) [a]	2.1	8.2	
		95% CI	(0.8, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.3190
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.214
		95% CI for Hazard Ratio			(0.429, 11.428)
		P-value of Subgroup*Treatment Interaction [d]			0.2445

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Yes	Number of Patients	158	145	
		Patients With Events (%)	90 (57.0)	88 (60.7)	
		Patients Without Events (Censored) (%)	68 (43.0)	57 (39.3)	
		Median Time (months) [a]	4.4	2.9	
		95% CI	(2.9, 6.6)	(2.1, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.0585
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.754
		95% CI for Hazard Ratio			(0.561, 1.013)
	No	Number of Patients	15	19	
		Patients With Events (%)	5 (33.3)	15 (78.9)	
		Patients Without Events (Censored) (%)	10 (66.7)	4 (21.1)	
		Median Time (months) [a]	8.1	1.5	
		95% CI	(1.7, NE)	(0.8, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.0016
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.194
		95% CI for Hazard Ratio			(0.063, 0.599)
		P-value of Subgroup*Treatment Interaction [d]			0.0287
Physical Functioning	Yes	Number of Patients	159	146	
		Patients With Events (%)	81 (50.9)	78 (53.4)	
		Patients Without Events (Censored) (%)	78 (49.1)	68 (46.6)	
		Median Time (months) [a]	5.9	3.4	
		95% CI	(3.0, 9.1)	(2.2, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.0661
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.747
		95% CI for Hazard Ratio			(0.546, 1.023)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	15	18	
		Patients With Events (%)	7 (46.7)	9 (50.0)	
		Patients Without Events (Censored) (%)	8 (53.3)	9 (50.0)	
		Median Time (months) [a]	5.1	4.6	
		95% CI	(1.7, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.4177
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.665
		95% CI for Hazard Ratio			(0.245, 1.801)
		P-value of Subgroup*Treatment Interaction [d]			0.9292
Role Functioning	Yes	Number of Patients	156	141	
		Patients With Events (%)	101 (64.7)	89 (63.1)	
		Patients Without Events (Censored) (%)	55 (35.3)	52 (36.9)	
		Median Time (months) [a]	2.8	2.2	
		95% CI	(1.7, 4.3)	(1.5, 3.3)	
		Log-rank p-value (Unstratified) [b]			0.1866
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.826
		95% CI for Hazard Ratio			(0.620, 1.101)
	No	Number of Patients	15	18	
		Patients With Events (%)	10 (66.7)	13 (72.2)	
		Patients Without Events (Censored) (%)	5 (33.3)	5 (27.8)	
		Median Time (months) [a]	4.4	1.5	
		95% CI	(1.6, 4.9)	(0.8, 2.7)	
		Log-rank p-value (Unstratified) [b]			0.0692
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.469
		95% CI for Hazard Ratio			(0.201, 1.094)
		P-value of Subgroup*Treatment Interaction [d]			0.3970

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Yes	Number of Patients	154	145	
		Patients With Events (%)	55 (35.7)	66 (45.5)	
		Patients Without Events (Censored) (%)	99 (64.3)	79 (54.5)	
		Median Time (months) [a]	NE	4.5	
		95% CI	(6.5, NE)	(3.4, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.0196
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.655
		95% CI for Hazard Ratio			(0.457, 0.938)
	No	Number of Patients	15	19	
		Patients With Events (%)	6 (40.0)	9 (47.4)	
		Patients Without Events (Censored) (%)	9 (60.0)	10 (52.6)	
		Median Time (months) [a]	NE	4.7	
		95% CI	(1.7, NE)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.2384
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.537
		95% CI for Hazard Ratio			(0.187, 1.541)
		P-value of Subgroup*Treatment Interaction [d]			0.7929
Cognitive Functioning	Yes	Number of Patients	159	145	
		Patients With Events (%)	78 (49.1)	61 (42.1)	
		Patients Without Events (Censored) (%)	81 (50.9)	84 (57.9)	
		Median Time (months) [a]	5.2	4.9	
		95% CI	(2.9, 11.1)	(3.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.9344
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.014
		95% CI for Hazard Ratio			(0.723, 1.422)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.3

Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months

EORTC QLQ-C30 Evaluable Population

Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization

Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	15	19	
		Patients With Events (%)	8 (53.3)	6 (31.6)	
		Patients Without Events (Censored) (%)	7 (46.7)	13 (68.4)	
		Median Time (months) [a]	5.0	5.4	
		95% CI	(1.7, NE)	(1.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.6914
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.240
		95% CI for Hazard Ratio			(0.425, 3.622)
		P-value of Subgroup*Treatment Interaction [d]			0.5869
Social Functioning	Yes	Number of Patients	155	140	
		Patients With Events (%)	93 (60.0)	78 (55.7)	
		Patients Without Events (Censored) (%)	62 (40.0)	62 (44.3)	
		Median Time (months) [a]	2.4	3.6	
		95% CI	(1.7, 4.3)	(2.6, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.9645
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.007
		95% CI for Hazard Ratio			(0.744, 1.363)
	No	Number of Patients	15	17	
		Patients With Events (%)	8 (53.3)	10 (58.8)	
		Patients Without Events (Censored) (%)	7 (46.7)	7 (41.2)	
		Median Time (months) [a]	2.3	2.7	
		95% CI	(1.0, NE)	(1.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.5858
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.773
		95% CI for Hazard Ratio			(0.303, 1.975)
		P-value of Subgroup*Treatment Interaction [d]			0.5636

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Yes	Number of Patients	157	145	
		Patients With Events (%)	112 (71.3)	108 (74.5)	
		Patients Without Events (Censored) (%)	45 (28.7)	37 (25.5)	
		Median Time (months) [a]	2.1	1.3	
		95% CI	(1.5, 2.9)	(1.0, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0194
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.732
		95% CI for Hazard Ratio			(0.560, 0.956)
	No	Number of Patients	15	17	
		Patients With Events (%)	9 (60.0)	16 (94.1)	
		Patients Without Events (Censored) (%)	6 (40.0)	1 (5.9)	
		Median Time (months) [a]	1.7	1.0	
		95% CI	(1.0, NE)	(0.8, 2.7)	
		Log-rank p-value (Unstratified) [b]			0.0173
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.375
		95% CI for Hazard Ratio			(0.159, 0.881)
		P-value of Subgroup*Treatment Interaction [d]			0.1890
Nausea and Vomiting	Yes	Number of Patients	158	146	
		Patients With Events (%)	98 (62.0)	67 (45.9)	
		Patients Without Events (Censored) (%)	60 (38.0)	79 (54.1)	
		Median Time (months) [a]	2.1	6.8	
		95% CI	(1.5, 3.9)	(3.5, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.0600
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.344
		95% CI for Hazard Ratio			(0.983, 1.837)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	15	19	
		Patients With Events (%)	8 (53.3)	10 (52.6)	
		Patients Without Events (Censored) (%)	7 (46.7)	9 (47.4)	
		Median Time (months) [a]	5.3	2.8	
		95% CI	(0.9, 18.2)	(1.4, 6.1)	
		Log-rank p-value (Unstratified) [b]			0.2905
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.591
		95% CI for Hazard Ratio			(0.221, 1.585)
		P-value of Subgroup*Treatment Interaction [d]			0.1850
Pain	Yes	Number of Patients	154	142	
		Patients With Events (%)	85 (55.2)	79 (55.6)	
		Patients Without Events (Censored) (%)	69 (44.8)	63 (44.4)	
		Median Time (months) [a]	4.0	3.3	
		95% CI	(2.8, 6.5)	(2.2, 5.7)	
		Log-rank p-value (Unstratified) [b]			0.2120
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.823
		95% CI for Hazard Ratio			(0.605, 1.121)
	No	Number of Patients	15	17	
		Patients With Events (%)	10 (66.7)	11 (64.7)	
		Patients Without Events (Censored) (%)	5 (33.3)	6 (35.3)	
		Median Time (months) [a]	2.8	2.7	
		95% CI	(1.0, 5.5)	(1.4, 4.7)	
		Log-rank p-value (Unstratified) [b]			0.8724
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.930
		95% CI for Hazard Ratio			(0.379, 2.278)
		P-value of Subgroup*Treatment Interaction [d]			0.5964

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Yes	Number of Patients	156	144	
		Patients With Events (%)	74 (47.4)	76 (52.8)	
		Patients Without Events (Censored) (%)	82 (52.6)	68 (47.2)	
		Median Time (months) [a]	6.6	3.7	
		95% CI	(4.3, 9.4)	(2.4, 7.5)	
		Log-rank p-value (Unstratified) [b]			0.0272
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.697
		95% CI for Hazard Ratio			(0.504, 0.963)
	No	Number of Patients	14	17	
		Patients With Events (%)	4 (28.6)	8 (47.1)	
		Patients Without Events (Censored) (%)	10 (71.4)	9 (52.9)	
		Median Time (months) [a]	NE	8.4	
		95% CI	(1.7, NE)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.2423
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.496
		95% CI for Hazard Ratio			(0.148, 1.662)
		P-value of Subgroup*Treatment Interaction [d]			0.3598
Insomnia	Yes	Number of Patients	145	132	
		Patients With Events (%)	61 (42.1)	60 (45.5)	
		Patients Without Events (Censored) (%)	84 (57.9)	72 (54.5)	
		Median Time (months) [a]	8.7	3.9	
		95% CI	(6.0, 23.6)	(3.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0419
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.691
		95% CI for Hazard Ratio			(0.482, 0.992)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	15	18	
		Patients With Events (%)	7 (46.7)	9 (50.0)	
		Patients Without Events (Censored) (%)	8 (53.3)	9 (50.0)	
		Median Time (months) [a]	5.9	2.1	
		95% CI	(1.7, 18.9)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.2009
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.507
		95% CI for Hazard Ratio			(0.175, 1.471)
		P-value of Subgroup*Treatment Interaction [d]			0.6854
Appetite Loss	Yes	Number of Patients	152	138	
		Patients With Events (%)	92 (60.5)	68 (49.3)	
		Patients Without Events (Censored) (%)	60 (39.5)	70 (50.7)	
		Median Time (months) [a]	2.8	4.4	
		95% CI	(1.7, 4.9)	(2.8, 5.6)	
		Log-rank p-value (Unstratified) [b]			0.2926
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.182
		95% CI for Hazard Ratio			(0.863, 1.620)
	No	Number of Patients	15	18	
		Patients With Events (%)	5 (33.3)	10 (55.6)	
		Patients Without Events (Censored) (%)	10 (66.7)	8 (44.4)	
		Median Time (months) [a]	18.2	1.6	
		95% CI	(5.0, 18.2)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.0390
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.309
		95% CI for Hazard Ratio			(0.094, 1.014)
		P-value of Subgroup*Treatment Interaction [d]			0.0462

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Yes	Number of Patients	155	140	
		Patients With Events (%)	76 (49.0)	62 (44.3)	
		Patients Without Events (Censored) (%)	79 (51.0)	78 (55.7)	
		Median Time (months) [a]	5.4	4.9	
		95% CI	(3.6, 9.1)	(3.2, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.7087
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.066
		95% CI for Hazard Ratio			(0.761, 1.491)
	No	Number of Patients	15	18	
		Patients With Events (%)	7 (46.7)	8 (44.4)	
		Patients Without Events (Censored) (%)	8 (53.3)	10 (55.6)	
		Median Time (months) [a]	2.8	3.5	
		95% CI	(1.6, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.6766
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.807
		95% CI for Hazard Ratio			(0.291, 2.242)
		P-value of Subgroup*Treatment Interaction [d]			0.4314
Diarrhea	Yes	Number of Patients	157	145	
		Patients With Events (%)	99 (63.1)	50 (34.5)	
		Patients Without Events (Censored) (%)	58 (36.9)	95 (65.5)	
		Median Time (months) [a]	1.9	8.2	
		95% CI	(1.5, 3.2)	(5.8, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.383
		95% CI for Hazard Ratio			(1.694, 3.352)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	15	19	
		Patients With Events (%)	5 (33.3)	5 (26.3)	
		Patients Without Events (Censored) (%)	10 (66.7)	14 (73.7)	
		Median Time (months) [a]	NE	7.7	
		95% CI	(1.4, NE)	(4.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.7443
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.230
		95% CI for Hazard Ratio			(0.352, 4.292)
		P-value of Subgroup*Treatment Interaction [d]			0.2576
Financial Difficulties	Yes	Number of Patients	154	140	
		Patients With Events (%)	39 (25.3)	28 (20.0)	
		Patients Without Events (Censored) (%)	115 (74.7)	112 (80.0)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(8.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.7487
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.082
		95% CI for Hazard Ratio			(0.664, 1.763)
	No	Number of Patients	15	19	
		Patients With Events (%)	4 (26.7)	3 (15.8)	
		Patients Without Events (Censored) (%)	11 (73.3)	16 (84.2)	
		Median Time (months) [a]	NE	NE	
		95% CI	(1.6, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.4942
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.677
		95% CI for Hazard Ratio			(0.375, 7.497)
		P-value of Subgroup*Treatment Interaction [d]			0.6976

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.3
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Endocrine therapy in the metastatic setting for at least 6 months
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Yes	Number of Patients	159	146	
		Patients With Events (%)	79 (49.7)	68 (46.6)	
		Patients Without Events (Censored) (%)	80 (50.3)	78 (53.4)	
		Median Time (months) [a]	5.6	5.3	
		95% CI	(3.7, 9.2)	(3.7, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.6392
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.925
		95% CI for Hazard Ratio			(0.668, 1.282)
	No	Number of Patients	15	19	
		Patients With Events (%)	6 (40.0)	11 (57.9)	
		Patients Without Events (Censored) (%)	9 (60.0)	8 (42.1)	
		Median Time (months) [a]	5.1	1.5	
		95% CI	(1.7, NE)	(1.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.0789
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.419
		95% CI for Hazard Ratio			(0.151, 1.160)
		P-value of Subgroup*Treatment Interaction [d]			0.1675

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	< 65 Years	Number of Patients	135	124	
		Patients With Events (%)	74 (54.8)	76 (61.3)	
		Patients Without Events (Censored) (%)	61 (45.2)	48 (38.7)	
		Median Time (months) [a]	5.4	2.7	
		95% CI	(3.0, 7.9)	(2.0, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.0171
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.676
		95% CI for Hazard Ratio			(0.488, 0.936)
	≥ 65 Years	Number of Patients	38	40	
		Patients With Events (%)	21 (55.3)	27 (67.5)	
		Patients Without Events (Censored) (%)	17 (44.7)	13 (32.5)	
		Median Time (months) [a]	3.2	2.2	
		95% CI	(1.5, NE)	(1.4, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.1284
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.646
		95% CI for Hazard Ratio			(0.365, 1.144)
		P-value of Subgroup*Treatment Interaction [d]			0.8062
Physical Functioning	< 65 Years	Number of Patients	136	124	
		Patients With Events (%)	72 (52.9)	70 (56.5)	
		Patients Without Events (Censored) (%)	64 (47.1)	54 (43.5)	
		Median Time (months) [a]	5.1	2.8	
		95% CI	(3.0, 7.4)	(2.1, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.0286
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.692
		95% CI for Hazard Ratio			(0.496, 0.966)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	≥ 65 Years	Number of Patients	38	40	
		Patients With Events (%)	16 (42.1)	17 (42.5)	
		Patients Without Events (Censored) (%)	22 (57.9)	23 (57.5)	
		Median Time (months) [a]	NE	6.0	
		95% CI	(2.1, NE)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.7530
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.896
		95% CI for Hazard Ratio			(0.452, 1.776)
		P-value of Subgroup*Treatment Interaction [d]			0.6138
Role Functioning	< 65 Years	Number of Patients	134	122	
		Patients With Events (%)	88 (65.7)	76 (62.3)	
		Patients Without Events (Censored) (%)	46 (34.3)	46 (37.7)	
		Median Time (months) [a]	2.6	2.0	
		95% CI	(1.7, 4.2)	(1.4, 3.1)	
		Log-rank p-value (Unstratified) [b]			0.1840
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.812
		95% CI for Hazard Ratio			(0.595, 1.109)
	≥ 65 Years	Number of Patients	37	37	
		Patients With Events (%)	23 (62.2)	26 (70.3)	
		Patients Without Events (Censored) (%)	14 (37.8)	11 (29.7)	
		Median Time (months) [a]	2.8	2.2	
		95% CI	(1.5, 7.0)	(1.5, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.2986
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.744
		95% CI for Hazard Ratio			(0.423, 1.307)
		P-value of Subgroup*Treatment Interaction [d]			0.7627

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	< 65 Years	Number of Patients	132	124	
		Patients With Events (%)	46 (34.8)	60 (48.4)	
		Patients Without Events (Censored) (%)	86 (65.2)	64 (51.6)	
		Median Time (months) [a]	12.8	4.3	
		95% CI	(6.1, NE)	(3.1, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.0030
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.562
		95% CI for Hazard Ratio			(0.381, 0.827)
	≥ 65 Years	Number of Patients	37	40	
		Patients With Events (%)	15 (40.5)	15 (37.5)	
		Patients Without Events (Censored) (%)	22 (59.5)	25 (62.5)	
		Median Time (months) [a]	NE	10.6	
		95% CI	(2.6, NE)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.8652
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.940
		95% CI for Hazard Ratio			(0.459, 1.924)
		P-value of Subgroup*Treatment Interaction [d]			0.2173
Cognitive Functioning	< 65 Years	Number of Patients	136	124	
		Patients With Events (%)	69 (50.7)	48 (38.7)	
		Patients Without Events (Censored) (%)	67 (49.3)	76 (61.3)	
		Median Time (months) [a]	4.1	7.2	
		95% CI	(2.8, 10.3)	(3.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.3960
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.173
		95% CI for Hazard Ratio			(0.810, 1.700)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	≥ 65 Years	Number of Patients	38	40	
		Patients With Events (%)	17 (44.7)	19 (47.5)	
		Patients Without Events (Censored) (%)	21 (55.3)	21 (52.5)	
		Median Time (months) [a]	18.8	4.3	
		95% CI	(2.1, NE)	(1.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.3657
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.737
		95% CI for Hazard Ratio			(0.378, 1.436)
		P-value of Subgroup*Treatment Interaction [d]			0.1812
Social Functioning	< 65 Years	Number of Patients	133	119	
		Patients With Events (%)	81 (60.9)	65 (54.6)	
		Patients Without Events (Censored) (%)	52 (39.1)	54 (45.4)	
		Median Time (months) [a]	2.4	3.7	
		95% CI	(1.7, 4.3)	(2.4, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.7963
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.044
		95% CI for Hazard Ratio			(0.751, 1.451)
	≥ 65 Years	Number of Patients	37	38	
		Patients With Events (%)	20 (54.1)	23 (60.5)	
		Patients Without Events (Censored) (%)	17 (45.9)	15 (39.5)	
		Median Time (months) [a]	2.1	3.0	
		95% CI	(1.4, NE)	(2.1, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.4388
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.789
		95% CI for Hazard Ratio			(0.431, 1.444)
		P-value of Subgroup*Treatment Interaction [d]			0.3532

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	< 65 Years	Number of Patients	134	122	
		Patients With Events (%)	94 (70.1)	96 (78.7)	
		Patients Without Events (Censored) (%)	40 (29.9)	26 (21.3)	
		Median Time (months) [a]	1.9	1.1	
		95% CI	(1.5, 2.8)	(0.9, 1.5)	
		Log-rank p-value (Unstratified) [b]			0.0031
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.655
		95% CI for Hazard Ratio			(0.491, 0.873)
	≥ 65 Years	Number of Patients	38	40	
		Patients With Events (%)	27 (71.1)	28 (70.0)	
		Patients Without Events (Censored) (%)	11 (28.9)	12 (30.0)	
		Median Time (months) [a]	2.2	1.9	
		95% CI	(0.9, 4.7)	(1.0, 2.8)	
		Log-rank p-value (Unstratified) [b]			0.3366
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.769
		95% CI for Hazard Ratio			(0.446, 1.325)
		P-value of Subgroup*Treatment Interaction [d]			0.6389
Nausea and Vomiting	< 65 Years	Number of Patients	135	125	
		Patients With Events (%)	89 (65.9)	61 (48.8)	
		Patients Without Events (Censored) (%)	46 (34.1)	64 (51.2)	
		Median Time (months) [a]	1.9	4.6	
		95% CI	(1.5, 3.2)	(2.8, 7.2)	
		Log-rank p-value (Unstratified) [b]			0.0506
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.379
		95% CI for Hazard Ratio			(0.994, 1.914)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	≥ 65 Years	Number of Patients	38	40	
		Patients With Events (%)	17 (44.7)	16 (40.0)	
		Patients Without Events (Censored) (%)	21 (55.3)	24 (60.0)	
		Median Time (months) [a]	14.4	9.5	
		95% CI	(1.5, NE)	(1.6, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.6725
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.862
		95% CI for Hazard Ratio			(0.429, 1.732)
		P-value of Subgroup*Treatment Interaction [d]			0.2572
Pain	< 65 Years	Number of Patients	132	119	
		Patients With Events (%)	75 (56.8)	63 (52.9)	
		Patients Without Events (Censored) (%)	57 (43.2)	56 (47.1)	
		Median Time (months) [a]	3.7	3.5	
		95% CI	(2.8, 6.2)	(2.7, 6.3)	
		Log-rank p-value (Unstratified) [b]			0.5300
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.898
		95% CI for Hazard Ratio			(0.640, 1.259)
	≥ 65 Years	Number of Patients	37	40	
		Patients With Events (%)	20 (54.1)	27 (67.5)	
		Patients Without Events (Censored) (%)	17 (45.9)	13 (32.5)	
		Median Time (months) [a]	5.0	2.2	
		95% CI	(1.2, NE)	(1.0, 3.2)	
		Log-rank p-value (Unstratified) [b]			0.1924
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.684
		95% CI for Hazard Ratio			(0.382, 1.223)
		P-value of Subgroup*Treatment Interaction [d]			0.4210

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	< 65 Years	Number of Patients	134	122	
		Patients With Events (%)	66 (49.3)	62 (50.8)	
		Patients Without Events (Censored) (%)	68 (50.7)	60 (49.2)	
		Median Time (months) [a]	5.8	3.7	
		95% CI	(3.4, 8.6)	(2.1, 7.5)	
		Log-rank p-value (Unstratified) [b]			0.1078
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.752
		95% CI for Hazard Ratio			(0.529, 1.068)
	≥ 65 Years	Number of Patients	36	39	
		Patients With Events (%)	12 (33.3)	22 (56.4)	
		Patients Without Events (Censored) (%)	24 (66.7)	17 (43.6)	
		Median Time (months) [a]	14.4	5.1	
		95% CI	(4.5, NE)	(1.9, 8.4)	
		Log-rank p-value (Unstratified) [b]			0.0320
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.469
		95% CI for Hazard Ratio			(0.231, 0.953)
		P-value of Subgroup*Treatment Interaction [d]			0.2548
Insomnia	< 65 Years	Number of Patients	123	115	
		Patients With Events (%)	56 (45.5)	53 (46.1)	
		Patients Without Events (Censored) (%)	67 (54.5)	62 (53.9)	
		Median Time (months) [a]	6.6	3.9	
		95% CI	(4.7, 18.9)	(2.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.1115
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.736
		95% CI for Hazard Ratio			(0.502, 1.079)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	≥ 65 Years	Number of Patients	37	35	
		Patients With Events (%)	12 (32.4)	16 (45.7)	
		Patients Without Events (Censored) (%)	25 (67.6)	19 (54.3)	
		Median Time (months) [a]	23.6	3.2	
		95% CI	(4.7, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.0291
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.434
		95% CI for Hazard Ratio			(0.200, 0.940)
		P-value of Subgroup*Treatment Interaction [d]			0.1920
Appetite Loss	< 65 Years	Number of Patients	129	118	
		Patients With Events (%)	75 (58.1)	60 (50.8)	
		Patients Without Events (Censored) (%)	54 (41.9)	58 (49.2)	
		Median Time (months) [a]	4.3	3.7	
		95% CI	(1.7, 6.0)	(2.2, 5.4)	
		Log-rank p-value (Unstratified) [b]			0.9526
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.990
		95% CI for Hazard Ratio			(0.702, 1.395)
	≥ 65 Years	Number of Patients	38	38	
		Patients With Events (%)	22 (57.9)	18 (47.4)	
		Patients Without Events (Censored) (%)	16 (42.1)	20 (52.6)	
		Median Time (months) [a]	2.1	3.6	
		95% CI	(1.2, NE)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.4355
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.279
		95% CI for Hazard Ratio			(0.685, 2.387)
		P-value of Subgroup*Treatment Interaction [d]			0.5420

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	< 65 Years	Number of Patients	134	119	
		Patients With Events (%)	66 (49.3)	58 (48.7)	
		Patients Without Events (Censored) (%)	68 (50.7)	61 (51.3)	
		Median Time (months) [a]	4.6	4.2	
		95% CI	(2.5, 8.6)	(3.0, 6.7)	
		Log-rank p-value (Unstratified) [b]			0.7487
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.944
		95% CI for Hazard Ratio			(0.663, 1.345)
	≥ 65 Years	Number of Patients	36	39	
		Patients With Events (%)	17 (47.2)	12 (30.8)	
		Patients Without Events (Censored) (%)	19 (52.8)	27 (69.2)	
		Median Time (months) [a]	14.4	NE	
		95% CI	(2.1, NE)	(3.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.4099
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.362
		95% CI for Hazard Ratio			(0.648, 2.863)
		P-value of Subgroup*Treatment Interaction [d]			0.3768
Diarrhea	< 65 Years	Number of Patients	134	124	
		Patients With Events (%)	82 (61.2)	44 (35.5)	
		Patients Without Events (Censored) (%)	52 (38.8)	80 (64.5)	
		Median Time (months) [a]	2.1	8.2	
		95% CI	(1.7, 3.4)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.115
		95% CI for Hazard Ratio			(1.465, 3.053)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	≥ 65 Years	Number of Patients	38	40	
		Patients With Events (%)	22 (57.9)	11 (27.5)	
		Patients Without Events (Censored) (%)	16 (42.1)	29 (72.5)	
		Median Time (months) [a]	1.5	10.9	
		95% CI	(1.0, NE)	(5.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0026
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.904
		95% CI for Hazard Ratio			(1.400, 6.025)
		P-value of Subgroup*Treatment Interaction [d]			0.4228
Financial Difficulties	< 65 Years	Number of Patients	131	120	
		Patients With Events (%)	34 (26.0)	27 (22.5)	
		Patients Without Events (Censored) (%)	97 (74.0)	93 (77.5)	
		Median Time (months) [a]	18.2	NE	
		95% CI	(18.2, NE)	(6.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.8593
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.955
		95% CI for Hazard Ratio			(0.573, 1.591)
	≥ 65 Years	Number of Patients	38	39	
		Patients With Events (%)	9 (23.7)	4 (10.3)	
		Patients Without Events (Censored) (%)	29 (76.3)	35 (89.7)	
		Median Time (months) [a]	NE	NE	
		95% CI	(7.2, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.1746
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.205
		95% CI for Hazard Ratio			(0.679, 7.164)
		P-value of Subgroup*Treatment Interaction [d]			0.2625

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.4
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Age group
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	< 65 Years	Number of Patients	136	125	
		Patients With Events (%)	66 (48.5)	59 (47.2)	
		Patients Without Events (Censored) (%)	70 (51.5)	66 (52.8)	
		Median Time (months) [a]	5.6	5.3	
		95% CI	(3.7, 8.3)	(3.1, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.3887
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.857
		95% CI for Hazard Ratio			(0.602, 1.220)
	≥ 65 Years	Number of Patients	38	40	
		Patients With Events (%)	19 (50.0)	20 (50.0)	
		Patients Without Events (Censored) (%)	19 (50.0)	20 (50.0)	
		Median Time (months) [a]	4.9	4.9	
		95% CI	(2.1, 23.6)	(2.2, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.7328
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.895
		95% CI for Hazard Ratio			(0.473, 1.695)
		P-value of Subgroup*Treatment Interaction [d]			0.9723

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	White	Number of Patients	124	112	
		Patients With Events (%)	66 (53.2)	70 (62.5)	
		Patients Without Events (Censored) (%)	58 (46.8)	42 (37.5)	
		Median Time (months) [a]	5.4	2.6	
		95% CI	(3.2, 9.1)	(1.8, 3.9)	
		Log-rank p-value (Unstratified) [b]			0.0066
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.628
		95% CI for Hazard Ratio			(0.447, 0.883)
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	5 (45.5)	11 (73.3)	
		Patients Without Events (Censored) (%)	6 (54.5)	4 (26.7)	
		Median Time (months) [a]	4.4	2.8	
		95% CI	(0.8, NE)	(1.3, 3.5)	
		Log-rank p-value (Unstratified) [b]			0.6470
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.781
		95% CI for Hazard Ratio			(0.269, 2.264)
		P-value of Subgroup*Treatment Interaction [d]			0.7755
Physical Functioning	White	Number of Patients	125	112	
		Patients With Events (%)	70 (56.0)	55 (49.1)	
		Patients Without Events (Censored) (%)	55 (44.0)	57 (50.9)	
		Median Time (months) [a]	4.0	3.5	
		95% CI	(2.9, 6.7)	(2.2, 6.7)	
		Log-rank p-value (Unstratified) [b]			0.5936
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.908
		95% CI for Hazard Ratio			(0.636, 1.296)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	3 (27.3)	9 (60.0)	
		Patients Without Events (Censored) (%)	8 (72.7)	6 (40.0)	
		Median Time (months) [a]	7.1	2.2	
		95% CI	(4.7, 12.5)	(1.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.0161
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.181
		95% CI for Hazard Ratio			(0.039, 0.854)
		P-value of Subgroup*Treatment Interaction [d]			0.0995
Role Functioning	White	Number of Patients	122	108	
		Patients With Events (%)	83 (68.0)	71 (65.7)	
		Patients Without Events (Censored) (%)	39 (32.0)	37 (34.3)	
		Median Time (months) [a]	2.8	1.7	
		95% CI	(1.7, 4.6)	(1.4, 2.8)	
		Log-rank p-value (Unstratified) [b]			0.0379
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.715
		95% CI for Hazard Ratio			(0.518, 0.987)
	Non-White	Number of Patients	11	14	
		Patients With Events (%)	9 (81.8)	10 (71.4)	
		Patients Without Events (Censored) (%)	2 (18.2)	4 (28.6)	
		Median Time (months) [a]	1.2	1.5	
		95% CI	(0.8, 4.2)	(0.8, 3.0)	
		Log-rank p-value (Unstratified) [b]			0.8889
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.069
		95% CI for Hazard Ratio			(0.419, 2.730)
		P-value of Subgroup*Treatment Interaction [d]			0.3035

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	White	Number of Patients	120	111	
		Patients With Events (%)	42 (35.0)	47 (42.3)	
		Patients Without Events (Censored) (%)	78 (65.0)	64 (57.7)	
		Median Time (months) [a]	NE	4.7	
		95% CI	(5.5, NE)	(3.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0581
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.671
		95% CI for Hazard Ratio			(0.442, 1.018)
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	5 (45.5)	7 (46.7)	
		Patients Without Events (Censored) (%)	6 (54.5)	8 (53.3)	
		Median Time (months) [a]	6.5	2.8	
		95% CI	(0.9, NE)	(1.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.8875
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.921
		95% CI for Hazard Ratio			(0.292, 2.906)
		P-value of Subgroup*Treatment Interaction [d]			0.6037
Cognitive Functioning	White	Number of Patients	125	111	
		Patients With Events (%)	63 (50.4)	43 (38.7)	
		Patients Without Events (Censored) (%)	62 (49.6)	68 (61.3)	
		Median Time (months) [a]	5.0	5.4	
		95% CI	(2.9, 10.3)	(3.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.7243
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.072
		95% CI for Hazard Ratio			(0.726, 1.584)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	3 (27.3)	6 (40.0)	
		Patients Without Events (Censored) (%)	8 (72.7)	9 (60.0)	
		Median Time (months) [a]	NE	4.9	
		95% CI	(1.0, NE)	(1.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.6104
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.699
		95% CI for Hazard Ratio			(0.174, 2.805)
		P-value of Subgroup*Treatment Interaction [d]			0.5738
Social Functioning	White	Number of Patients	122	105	
		Patients With Events (%)	74 (60.7)	61 (58.1)	
		Patients Without Events (Censored) (%)	48 (39.3)	44 (41.9)	
		Median Time (months) [a]	2.3	2.9	
		95% CI	(1.7, 4.6)	(2.3, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.8769
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.974
		95% CI for Hazard Ratio			(0.692, 1.369)
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	6 (54.5)	6 (40.0)	
		Patients Without Events (Censored) (%)	5 (45.5)	9 (60.0)	
		Median Time (months) [a]	1.9	3.1	
		95% CI	(1.0, 12.5)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.9244
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.059
		95% CI for Hazard Ratio			(0.322, 3.479)
		P-value of Subgroup*Treatment Interaction [d]			0.7261

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	White	Number of Patients	123	110	
		Patients With Events (%)	86 (69.9)	85 (77.3)	
		Patients Without Events (Censored) (%)	37 (30.1)	25 (22.7)	
		Median Time (months) [a]	2.6	1.1	
		95% CI	(1.7, 3.7)	(1.0, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0026
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.634
		95% CI for Hazard Ratio			(0.468, 0.859)
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	6 (54.5)	11 (73.3)	
		Patients Without Events (Censored) (%)	5 (45.5)	4 (26.7)	
		Median Time (months) [a]	1.9	1.2	
		95% CI	(0.9, NE)	(0.8, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.4824
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.702
		95% CI for Hazard Ratio			(0.257, 1.919)
		P-value of Subgroup*Treatment Interaction [d]			0.9068
Nausea and Vomiting	White	Number of Patients	124	112	
		Patients With Events (%)	73 (58.9)	53 (47.3)	
		Patients Without Events (Censored) (%)	51 (41.1)	59 (52.7)	
		Median Time (months) [a]	3.1	4.6	
		95% CI	(1.7, 4.9)	(2.7, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.4544
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.143
		95% CI for Hazard Ratio			(0.801, 1.633)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	5 (45.5)	5 (33.3)	
		Patients Without Events (Censored) (%)	6 (54.5)	10 (66.7)	
		Median Time (months) [a]	4.2	NE	
		95% CI	(0.8, NE)	(1.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.4584
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.587
		95% CI for Hazard Ratio			(0.458, 5.494)
		P-value of Subgroup*Treatment Interaction [d]			0.6207
Pain	White	Number of Patients	122	107	
		Patients With Events (%)	70 (57.4)	58 (54.2)	
		Patients Without Events (Censored) (%)	52 (42.6)	49 (45.8)	
		Median Time (months) [a]	4.8	3.3	
		95% CI	(2.8, 6.5)	(2.2, 5.7)	
		Log-rank p-value (Unstratified) [b]			0.3163
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.837
		95% CI for Hazard Ratio			(0.589, 1.189)
	Non-White	Number of Patients	10	15	
		Patients With Events (%)	6 (60.0)	8 (53.3)	
		Patients Without Events (Censored) (%)	4 (40.0)	7 (46.7)	
		Median Time (months) [a]	2.4	2.2	
		95% CI	(0.8, NE)	(1.0, 9.8)	
		Log-rank p-value (Unstratified) [b]			0.5294
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.418
		95% CI for Hazard Ratio			(0.475, 4.230)
		P-value of Subgroup*Treatment Interaction [d]			0.3582

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	White	Number of Patients	121	109	
		Patients With Events (%)	57 (47.1)	54 (49.5)	
		Patients Without Events (Censored) (%)	64 (52.9)	55 (50.5)	
		Median Time (months) [a]	6.7	3.7	
		95% CI	(4.5, 14.4)	(2.1, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.0512
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.690
		95% CI for Hazard Ratio			(0.473, 1.006)
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	4 (36.4)	11 (73.3)	
		Patients Without Events (Censored) (%)	7 (63.6)	4 (26.7)	
		Median Time (months) [a]	5.8	2.2	
		95% CI	(0.9, NE)	(0.8, 5.6)	
		Log-rank p-value (Unstratified) [b]			0.1543
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.447
		95% CI for Hazard Ratio			(0.142, 1.407)
		P-value of Subgroup*Treatment Interaction [d]			0.5249
Insomnia	White	Number of Patients	116	103	
		Patients With Events (%)	52 (44.8)	47 (45.6)	
		Patients Without Events (Censored) (%)	64 (55.2)	56 (54.4)	
		Median Time (months) [a]	7.7	3.5	
		95% CI	(4.7, 23.6)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.0634
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.687
		95% CI for Hazard Ratio			(0.460, 1.026)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Non-White	Number of Patients	10	13	
		Patients With Events (%)	4 (40.0)	5 (38.5)	
		Patients Without Events (Censored) (%)	6 (60.0)	8 (61.5)	
		Median Time (months) [a]	12.5	NE	
		95% CI	(1.0, 12.5)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.6423
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.714
		95% CI for Hazard Ratio			(0.170, 2.997)
		P-value of Subgroup*Treatment Interaction [d]			0.6723
Appetite Loss	White	Number of Patients	120	106	
		Patients With Events (%)	67 (55.8)	51 (48.1)	
		Patients Without Events (Censored) (%)	53 (44.2)	55 (51.9)	
		Median Time (months) [a]	4.3	4.9	
		95% CI	(1.9, 7.4)	(3.1, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.9088
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.022
		95% CI for Hazard Ratio			(0.708, 1.475)
	Non-White	Number of Patients	10	13	
		Patients With Events (%)	7 (70.0)	8 (61.5)	
		Patients Without Events (Censored) (%)	3 (30.0)	5 (38.5)	
		Median Time (months) [a]	1.2	2.3	
		95% CI	(0.8, 3.3)	(1.0, 3.1)	
		Log-rank p-value (Unstratified) [b]			0.6100
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.305
		95% CI for Hazard Ratio			(0.465, 3.662)
		P-value of Subgroup*Treatment Interaction [d]			0.5153

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	White	Number of Patients	121	106	
		Patients With Events (%)	60 (49.6)	51 (48.1)	
		Patients Without Events (Censored) (%)	61 (50.4)	55 (51.9)	
		Median Time (months) [a]	4.6	3.7	
		95% CI	(2.8, 14.4)	(2.4, 6.7)	
		Log-rank p-value (Unstratified) [b]			0.6096
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.908
		95% CI for Hazard Ratio			(0.624, 1.320)
	Non-White	Number of Patients	11	14	
		Patients With Events (%)	6 (54.5)	5 (35.7)	
		Patients Without Events (Censored) (%)	5 (45.5)	9 (64.3)	
		Median Time (months) [a]	9.1	4.2	
		95% CI	(0.8, 13.9)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.6908
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.289
		95% CI for Hazard Ratio			(0.366, 4.538)
		P-value of Subgroup*Treatment Interaction [d]			0.2838
Diarrhea	White	Number of Patients	123	111	
		Patients With Events (%)	73 (59.3)	36 (32.4)	
		Patients Without Events (Censored) (%)	50 (40.7)	75 (67.6)	
		Median Time (months) [a]	2.1	10.9	
		95% CI	(1.7, 4.0)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.211
		95% CI for Hazard Ratio			(1.482, 3.299)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	5 (45.5)	4 (26.7)	
		Patients Without Events (Censored) (%)	6 (54.5)	11 (73.3)	
		Median Time (months) [a]	3.4	NE	
		95% CI	(0.8, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.5129
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.555
		95% CI for Hazard Ratio			(0.408, 5.935)
		P-value of Subgroup*Treatment Interaction [d]			0.8456
Financial Difficulties	White	Number of Patients	123	109	
		Patients With Events (%)	32 (26.0)	27 (24.8)	
		Patients Without Events (Censored) (%)	91 (74.0)	82 (75.2)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(6.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.5623
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.859
		95% CI for Hazard Ratio			(0.512, 1.441)
	Non-White	Number of Patients	10	13	
		Patients With Events (%)	3 (30.0)	1 (7.7)	
		Patients Without Events (Censored) (%)	7 (70.0)	12 (92.3)	
		Median Time (months) [a]	5.8	NE	
		95% CI	(1.0, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.1673
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			4.344
		95% CI for Hazard Ratio			(0.448, 42.132)
		P-value of Subgroup*Treatment Interaction [d]			0.1620

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.5
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Race
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	White	Number of Patients	125	112	
		Patients With Events (%)	58 (46.4)	50 (44.6)	
		Patients Without Events (Censored) (%)	67 (53.6)	62 (55.4)	
		Median Time (months) [a]	6.6	6.4	
		95% CI	(3.9, 23.6)	(3.7, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.3222
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.826
		95% CI for Hazard Ratio			(0.564, 1.209)
	Non-White	Number of Patients	11	15	
		Patients With Events (%)	5 (45.5)	9 (60.0)	
		Patients Without Events (Censored) (%)	6 (54.5)	6 (40.0)	
		Median Time (months) [a]	6.5	2.8	
		95% CI	(0.8, NE)	(1.0, 3.1)	
		Log-rank p-value (Unstratified) [b]			0.5095
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.688
		95% CI for Hazard Ratio			(0.224, 2.109)
		P-value of Subgroup*Treatment Interaction [d]			0.8665

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	0	Number of Patients	77	78	
		Patients With Events (%)	48 (62.3)	51 (65.4)	
		Patients Without Events (Censored) (%)	29 (37.7)	27 (34.6)	
		Median Time (months) [a]	4.0	3.0	
		95% CI	(1.7, 7.9)	(2.0, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.1684
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.757
		95% CI for Hazard Ratio			(0.507, 1.129)
	1	Number of Patients	96	86	
		Patients With Events (%)	47 (49.0)	52 (60.5)	
		Patients Without Events (Censored) (%)	49 (51.0)	34 (39.5)	
		Median Time (months) [a]	5.0	2.2	
		95% CI	(3.1, 8.0)	(1.4, 3.3)	
		Log-rank p-value (Unstratified) [b]			0.0132
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.610
		95% CI for Hazard Ratio			(0.410, 0.908)
		P-value of Subgroup*Treatment Interaction [d]			0.4222
Physical Functioning	0	Number of Patients	77	77	
		Patients With Events (%)	40 (51.9)	40 (51.9)	
		Patients Without Events (Censored) (%)	37 (48.1)	37 (48.1)	
		Median Time (months) [a]	5.9	3.5	
		95% CI	(3.0, 13.1)	(2.2, 6.0)	
		Log-rank p-value (Unstratified) [b]			0.0933
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.682
		95% CI for Hazard Ratio			(0.434, 1.071)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	1	Number of Patients	97	87	
		Patients With Events (%)	48 (49.5)	47 (54.0)	
		Patients Without Events (Censored) (%)	49 (50.5)	40 (46.0)	
		Median Time (months) [a]	4.7	3.0	
		95% CI	(2.6, 7.4)	(2.1, 6.2)	
		Log-rank p-value (Unstratified) [b]			0.2555
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.793
		95% CI for Hazard Ratio			(0.530, 1.187)
		P-value of Subgroup*Treatment Interaction [d]			0.7073
Role Functioning	0	Number of Patients	77	75	
		Patients With Events (%)	48 (62.3)	46 (61.3)	
		Patients Without Events (Censored) (%)	29 (37.7)	29 (38.7)	
		Median Time (months) [a]	2.9	2.8	
		95% CI	(1.7, 5.9)	(1.4, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.2274
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.779
		95% CI for Hazard Ratio			(0.517, 1.174)
	1	Number of Patients	94	84	
		Patients With Events (%)	63 (67.0)	56 (66.7)	
		Patients Without Events (Censored) (%)	31 (33.0)	28 (33.3)	
		Median Time (months) [a]	2.3	2.1	
		95% CI	(1.7, 4.5)	(1.4, 3.0)	
		Log-rank p-value (Unstratified) [b]			0.2423
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.808
		95% CI for Hazard Ratio			(0.562, 1.162)
		P-value of Subgroup*Treatment Interaction [d]			0.7488

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	0	Number of Patients	75	78	
		Patients With Events (%)	21 (28.0)	33 (42.3)	
		Patients Without Events (Censored) (%)	54 (72.0)	45 (57.7)	
		Median Time (months) [a]	NE	4.7	
		95% CI	(8.9, NE)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.0053
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.464
		95% CI for Hazard Ratio			(0.267, 0.807)
	1	Number of Patients	94	86	
		Patients With Events (%)	40 (42.6)	42 (48.8)	
		Patients Without Events (Censored) (%)	54 (57.4)	44 (51.2)	
		Median Time (months) [a]	6.5	4.2	
		95% CI	(2.8, NE)	(2.4, 7.2)	
		Log-rank p-value (Unstratified) [b]			0.2837
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.790
		95% CI for Hazard Ratio			(0.512, 1.219)
		P-value of Subgroup*Treatment Interaction [d]			0.1506
Cognitive Functioning	0	Number of Patients	77	77	
		Patients With Events (%)	43 (55.8)	31 (40.3)	
		Patients Without Events (Censored) (%)	34 (44.2)	46 (59.7)	
		Median Time (months) [a]	4.1	8.2	
		95% CI	(2.7, 11.1)	(4.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.7107
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.092
		95% CI for Hazard Ratio			(0.683, 1.744)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	1	Number of Patients	97	87	
		Patients With Events (%)	43 (44.3)	36 (41.4)	
		Patients Without Events (Censored) (%)	54 (55.7)	51 (58.6)	
		Median Time (months) [a]	6.6	4.3	
		95% CI	(2.8, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.9512
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.986
		95% CI for Hazard Ratio			(0.632, 1.540)
		P-value of Subgroup*Treatment Interaction [d]			0.7696
Social Functioning	0	Number of Patients	76	74	
		Patients With Events (%)	43 (56.6)	37 (50.0)	
		Patients Without Events (Censored) (%)	33 (43.4)	37 (50.0)	
		Median Time (months) [a]	4.7	4.2	
		95% CI	(1.8, 9.5)	(2.9, 5.2)	
		Log-rank p-value (Unstratified) [b]			0.6522
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.901
		95% CI for Hazard Ratio			(0.572, 1.418)
	1	Number of Patients	94	83	
		Patients With Events (%)	58 (61.7)	51 (61.4)	
		Patients Without Events (Censored) (%)	36 (38.3)	32 (38.6)	
		Median Time (months) [a]	2.0	2.7	
		95% CI	(1.5, 2.9)	(1.5, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.9890
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.997
		95% CI for Hazard Ratio			(0.684, 1.454)
		P-value of Subgroup*Treatment Interaction [d]			0.8440

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	0	Number of Patients	77	77	
		Patients With Events (%)	56 (72.7)	58 (75.3)	
		Patients Without Events (Censored) (%)	21 (27.3)	19 (24.7)	
		Median Time (months) [a]	1.7	1.2	
		95% CI	(1.4, 4.0)	(1.0, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.0310
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.669
		95% CI for Hazard Ratio			(0.460, 0.972)
	1	Number of Patients	95	85	
		Patients With Events (%)	65 (68.4)	66 (77.6)	
		Patients Without Events (Censored) (%)	30 (31.6)	19 (22.4)	
		Median Time (months) [a]	2.2	1.3	
		95% CI	(1.4, 2.8)	(1.0, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0431
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.706
		95% CI for Hazard Ratio			(0.500, 0.996)
		P-value of Subgroup*Treatment Interaction [d]			0.8641
Nausea and Vomiting	0	Number of Patients	77	78	
		Patients With Events (%)	46 (59.7)	34 (43.6)	
		Patients Without Events (Censored) (%)	31 (40.3)	44 (56.4)	
		Median Time (months) [a]	2.6	6.8	
		95% CI	(1.5, 7.4)	(3.0, 10.3)	
		Log-rank p-value (Unstratified) [b]			0.4020
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.211
		95% CI for Hazard Ratio			(0.770, 1.902)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	1	Number of Patients	96	87	
		Patients With Events (%)	60 (62.5)	43 (49.4)	
		Patients Without Events (Censored) (%)	36 (37.5)	44 (50.6)	
		Median Time (months) [a]	2.1	4.6	
		95% CI	(1.4, 3.9)	(1.6, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.1880
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.296
		95% CI for Hazard Ratio			(0.876, 1.918)
		P-value of Subgroup*Treatment Interaction [d]			0.8256
Pain	0	Number of Patients	77	76	
		Patients With Events (%)	41 (53.2)	42 (55.3)	
		Patients Without Events (Censored) (%)	36 (46.8)	34 (44.7)	
		Median Time (months) [a]	6.1	4.3	
		95% CI	(3.7, 9.7)	(1.7, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.2096
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.760
		95% CI for Hazard Ratio			(0.493, 1.173)
	1	Number of Patients	92	83	
		Patients With Events (%)	54 (58.7)	48 (57.8)	
		Patients Without Events (Censored) (%)	38 (41.3)	35 (42.2)	
		Median Time (months) [a]	2.9	3.1	
		95% CI	(1.9, 4.8)	(2.2, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.6378
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.911
		95% CI for Hazard Ratio			(0.615, 1.348)
		P-value of Subgroup*Treatment Interaction [d]			0.4996

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	0	Number of Patients	77	75	
		Patients With Events (%)	32 (41.6)	35 (46.7)	
		Patients Without Events (Censored) (%)	45 (58.4)	40 (53.3)	
		Median Time (months) [a]	9.5	4.3	
		95% CI	(5.8, NE)	(2.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.0698
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.640
		95% CI for Hazard Ratio			(0.393, 1.043)
	1	Number of Patients	93	86	
		Patients With Events (%)	46 (49.5)	49 (57.0)	
		Patients Without Events (Censored) (%)	47 (50.5)	37 (43.0)	
		Median Time (months) [a]	5.0	3.0	
		95% CI	(3.1, 9.4)	(1.7, 7.5)	
		Log-rank p-value (Unstratified) [b]			0.1072
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.719
		95% CI for Hazard Ratio			(0.479, 1.078)
		P-value of Subgroup*Treatment Interaction [d]			0.6701
Insomnia	0	Number of Patients	72	71	
		Patients With Events (%)	27 (37.5)	30 (42.3)	
		Patients Without Events (Censored) (%)	45 (62.5)	41 (57.7)	
		Median Time (months) [a]	18.9	NE	
		95% CI	(6.3, NE)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.1199
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.661
		95% CI for Hazard Ratio			(0.388, 1.124)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	1	Number of Patients	88	79	
		Patients With Events (%)	41 (46.6)	39 (49.4)	
		Patients Without Events (Censored) (%)	47 (53.4)	40 (50.6)	
		Median Time (months) [a]	6.0	3.3	
		95% CI	(4.1, 8.7)	(2.0, 7.4)	
		Log-rank p-value (Unstratified) [b]			0.0744
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.671
		95% CI for Hazard Ratio			(0.431, 1.047)
		P-value of Subgroup*Treatment Interaction [d]			0.7207
Appetite Loss	0	Number of Patients	76	73	
		Patients With Events (%)	44 (57.9)	36 (49.3)	
		Patients Without Events (Censored) (%)	32 (42.1)	37 (50.7)	
		Median Time (months) [a]	5.0	4.7	
		95% CI	(1.8, 9.1)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.9492
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.986
		95% CI for Hazard Ratio			(0.629, 1.544)
	1	Number of Patients	91	83	
		Patients With Events (%)	53 (58.2)	42 (50.6)	
		Patients Without Events (Censored) (%)	38 (41.8)	41 (49.4)	
		Median Time (months) [a]	2.8	3.0	
		95% CI	(1.7, 5.9)	(2.1, 5.4)	
		Log-rank p-value (Unstratified) [b]			0.5918
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.116
		95% CI for Hazard Ratio			(0.743, 1.677)
		P-value of Subgroup*Treatment Interaction [d]			0.6317

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	0	Number of Patients	77	73	
		Patients With Events (%)	37 (48.1)	26 (35.6)	
		Patients Without Events (Censored) (%)	40 (51.9)	47 (64.4)	
		Median Time (months) [a]	8.6	6.7	
		95% CI	(2.5, NE)	(3.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.3231
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.287
		95% CI for Hazard Ratio			(0.777, 2.129)
	1	Number of Patients	93	85	
		Patients With Events (%)	46 (49.5)	44 (51.8)	
		Patients Without Events (Censored) (%)	47 (50.5)	41 (48.2)	
		Median Time (months) [a]	4.5	3.2	
		95% CI	(2.4, 9.1)	(1.9, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.4499
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.853
		95% CI for Hazard Ratio			(0.564, 1.291)
		P-value of Subgroup*Treatment Interaction [d]			0.1859
Diarrhea	0	Number of Patients	77	77	
		Patients With Events (%)	47 (61.0)	20 (26.0)	
		Patients Without Events (Censored) (%)	30 (39.0)	57 (74.0)	
		Median Time (months) [a]	2.0	NE	
		95% CI	(1.5, 4.0)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			3.026
		95% CI for Hazard Ratio			(1.790, 5.115)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	1	Number of Patients	95	87	
		Patients With Events (%)	57 (60.0)	35 (40.2)	
		Patients Without Events (Censored) (%)	38 (40.0)	52 (59.8)	
		Median Time (months) [a]	2.1	7.7	
		95% CI	(1.5, 3.9)	(5.1, 10.9)	
		Log-rank p-value (Unstratified) [b]			0.0045
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.818
		95% CI for Hazard Ratio			(1.192, 2.773)
		P-value of Subgroup*Treatment Interaction [d]			0.1349
Financial Difficulties	0	Number of Patients	76	77	
		Patients With Events (%)	18 (23.7)	13 (16.9)	
		Patients Without Events (Censored) (%)	58 (76.3)	64 (83.1)	
		Median Time (months) [a]	NE	NE	
		95% CI	(NE, NE)	(8.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.6708
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.168
		95% CI for Hazard Ratio			(0.570, 2.390)
	1	Number of Patients	93	82	
		Patients With Events (%)	25 (26.9)	18 (22.0)	
		Patients Without Events (Censored) (%)	68 (73.1)	64 (78.0)	
		Median Time (months) [a]	18.2	NE	
		95% CI	(7.2, NE)	(6.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.8381
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.065
		95% CI for Hazard Ratio			(0.578, 1.964)
		P-value of Subgroup*Treatment Interaction [d]			0.9542

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.6
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline ECOG status
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	0	Number of Patients	77	78	
		Patients With Events (%)	40 (51.9)	33 (42.3)	
		Patients Without Events (Censored) (%)	37 (48.1)	45 (57.7)	
		Median Time (months) [a]	5.9	8.2	
		95% CI	(2.9, 23.6)	(4.3, 9.9)	
		Log-rank p-value (Unstratified) [b]			0.9812
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.994
		95% CI for Hazard Ratio			(0.623, 1.587)
	1	Number of Patients	97	87	
		Patients With Events (%)	45 (46.4)	46 (52.9)	
		Patients Without Events (Censored) (%)	52 (53.6)	41 (47.1)	
		Median Time (months) [a]	4.9	3.5	
		95% CI	(3.2, 9.2)	(2.2, 7.2)	
		Log-rank p-value (Unstratified) [b]			0.1926
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.762
		95% CI for Hazard Ratio			(0.505, 1.150)
		P-value of Subgroup*Treatment Interaction [d]			0.4372

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Europe	Number of Patients	105	105	
		Patients With Events (%)	64 (61.0)	66 (62.9)	
		Patients Without Events (Censored) (%)	41 (39.0)	39 (37.1)	
		Median Time (months) [a]	3.2	2.7	
		95% CI	(2.1, 5.9)	(1.9, 3.9)	
		Log-rank p-value (Unstratified) [b]			0.1862
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.793
		95% CI for Hazard Ratio			(0.561, 1.122)
	North America	Number of Patients	68	59	
		Patients With Events (%)	31 (45.6)	37 (62.7)	
		Patients Without Events (Censored) (%)	37 (54.4)	22 (37.3)	
		Median Time (months) [a]	6.6	2.6	
		95% CI	(3.4, NE)	(1.5, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.0078
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.527
		95% CI for Hazard Ratio			(0.325, 0.853)
		P-value of Subgroup*Treatment Interaction [d]			0.1297
Physical Functioning	Europe	Number of Patients	106	105	
		Patients With Events (%)	53 (50.0)	54 (51.4)	
		Patients Without Events (Censored) (%)	53 (50.0)	51 (48.6)	
		Median Time (months) [a]	5.1	3.5	
		95% CI	(2.8, 13.1)	(2.2, 6.2)	
		Log-rank p-value (Unstratified) [b]			0.2792
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.812
		95% CI for Hazard Ratio			(0.555, 1.188)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	North America	Number of Patients	68	59	
		Patients With Events (%)	35 (51.5)	33 (55.9)	
		Patients Without Events (Censored) (%)	33 (48.5)	26 (44.1)	
		Median Time (months) [a]	6.6	3.0	
		95% CI	(3.1, 9.1)	(1.9, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.0652
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.637
		95% CI for Hazard Ratio			(0.392, 1.036)
		P-value of Subgroup*Treatment Interaction [d]			0.5485
Role Functioning	Europe	Number of Patients	103	101	
		Patients With Events (%)	66 (64.1)	60 (59.4)	
		Patients Without Events (Censored) (%)	37 (35.9)	41 (40.6)	
		Median Time (months) [a]	2.8	2.8	
		95% CI	(1.7, 4.4)	(1.8, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.6263
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.917
		95% CI for Hazard Ratio			(0.645, 1.304)
	North America	Number of Patients	68	58	
		Patients With Events (%)	45 (66.2)	42 (72.4)	
		Patients Without Events (Censored) (%)	23 (33.8)	16 (27.6)	
		Median Time (months) [a]	2.1	1.5	
		95% CI	(1.5, 4.8)	(1.3, 2.8)	
		Log-rank p-value (Unstratified) [b]			0.0167
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.596
		95% CI for Hazard Ratio			(0.387, 0.918)
		P-value of Subgroup*Treatment Interaction [d]			0.1617

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Europe	Number of Patients	101	105	
		Patients With Events (%)	38 (37.6)	49 (46.7)	
		Patients Without Events (Censored) (%)	63 (62.4)	56 (53.3)	
		Median Time (months) [a]	8.9	4.4	
		95% CI	(5.1, NE)	(3.3, 10.6)	
		Log-rank p-value (Unstratified) [b]			0.0659
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.674
		95% CI for Hazard Ratio			(0.440, 1.031)
	North America	Number of Patients	68	59	
		Patients With Events (%)	23 (33.8)	26 (44.1)	
		Patients Without Events (Censored) (%)	45 (66.2)	33 (55.9)	
		Median Time (months) [a]	NE	4.7	
		95% CI	(4.0, NE)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.0809
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.610
		95% CI for Hazard Ratio			(0.347, 1.071)
		P-value of Subgroup*Treatment Interaction [d]			0.6971
Cognitive Functioning	Europe	Number of Patients	106	105	
		Patients With Events (%)	52 (49.1)	42 (40.0)	
		Patients Without Events (Censored) (%)	54 (50.9)	63 (60.0)	
		Median Time (months) [a]	5.6	8.2	
		95% CI	(2.9, 15.2)	(3.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.7697
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.063
		95% CI for Hazard Ratio			(0.704, 1.604)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	North America	Number of Patients	68	59	
		Patients With Events (%)	34 (50.0)	25 (42.4)	
		Patients Without Events (Censored) (%)	34 (50.0)	34 (57.6)	
		Median Time (months) [a]	4.1	4.3	
		95% CI	(2.6, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.9853
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.005
		95% CI for Hazard Ratio			(0.599, 1.686)
		P-value of Subgroup*Treatment Interaction [d]			0.7051
Social Functioning	Europe	Number of Patients	102	98	
		Patients With Events (%)	61 (59.8)	58 (59.2)	
		Patients Without Events (Censored) (%)	41 (40.2)	40 (40.8)	
		Median Time (months) [a]	2.9	3.6	
		95% CI	(1.7, 4.6)	(2.3, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.6143
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.911
		95% CI for Hazard Ratio			(0.634, 1.311)
	North America	Number of Patients	68	59	
		Patients With Events (%)	40 (58.8)	30 (50.8)	
		Patients Without Events (Censored) (%)	28 (41.2)	29 (49.2)	
		Median Time (months) [a]	2.0	3.1	
		95% CI	(1.6, 6.0)	(2.1, 5.8)	
		Log-rank p-value (Unstratified) [b]			0.6893
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.101
		95% CI for Hazard Ratio			(0.684, 1.772)
		P-value of Subgroup*Treatment Interaction [d]			0.6579

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Europe	Number of Patients	105	103	
		Patients With Events (%)	75 (71.4)	77 (74.8)	
		Patients Without Events (Censored) (%)	30 (28.6)	26 (25.2)	
		Median Time (months) [a]	2.0	1.6	
		95% CI	(1.4, 2.8)	(1.0, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.1791
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.806
		95% CI for Hazard Ratio			(0.585, 1.110)
	North America	Number of Patients	67	59	
		Patients With Events (%)	46 (68.7)	47 (79.7)	
		Patients Without Events (Censored) (%)	21 (31.3)	12 (20.3)	
		Median Time (months) [a]	2.1	1.0	
		95% CI	(1.5, 4.2)	(0.9, 1.3)	
		Log-rank p-value (Unstratified) [b]			0.0014
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.517
		95% CI for Hazard Ratio			(0.340, 0.784)
		P-value of Subgroup*Treatment Interaction [d]			0.0966
Nausea and Vomiting	Europe	Number of Patients	106	106	
		Patients With Events (%)	67 (63.2)	49 (46.2)	
		Patients Without Events (Censored) (%)	39 (36.8)	57 (53.8)	
		Median Time (months) [a]	2.0	4.6	
		95% CI	(1.5, 3.5)	(2.9, 10.3)	
		Log-rank p-value (Unstratified) [b]			0.0656
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.409
		95% CI for Hazard Ratio			(0.972, 2.043)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	North America	Number of Patients	67	59	
		Patients With Events (%)	39 (58.2)	28 (47.5)	
		Patients Without Events (Censored) (%)	28 (41.8)	31 (52.5)	
		Median Time (months) [a]	4.1	6.1	
		95% CI	(1.4, 8.0)	(1.6, 10.1)	
		Log-rank p-value (Unstratified) [b]			0.7984
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.065
		95% CI for Hazard Ratio			(0.652, 1.741)
		P-value of Subgroup*Treatment Interaction [d]			0.4026
Pain	Europe	Number of Patients	103	100	
		Patients With Events (%)	56 (54.4)	56 (56.0)	
		Patients Without Events (Censored) (%)	47 (45.6)	44 (44.0)	
		Median Time (months) [a]	3.8	2.8	
		95% CI	(2.8, 6.2)	(2.1, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.2984
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.822
		95% CI for Hazard Ratio			(0.566, 1.195)
	North America	Number of Patients	66	59	
		Patients With Events (%)	39 (59.1)	34 (57.6)	
		Patients Without Events (Censored) (%)	27 (40.9)	25 (42.4)	
		Median Time (months) [a]	3.7	3.4	
		95% CI	(1.7, 9.1)	(2.2, 5.7)	
		Log-rank p-value (Unstratified) [b]			0.4767
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.846
		95% CI for Hazard Ratio			(0.531, 1.346)
		P-value of Subgroup*Treatment Interaction [d]			0.9030

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Europe	Number of Patients	103	103	
		Patients With Events (%)	47 (45.6)	55 (53.4)	
		Patients Without Events (Censored) (%)	56 (54.4)	48 (46.6)	
		Median Time (months) [a]	6.7	4.3	
		95% CI	(3.5, NE)	(2.4, 7.7)	
		Log-rank p-value (Unstratified) [b]			0.0454
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.672
		95% CI for Hazard Ratio			(0.452, 0.997)
	North America	Number of Patients	67	58	
		Patients With Events (%)	31 (46.3)	29 (50.0)	
		Patients Without Events (Censored) (%)	36 (53.7)	29 (50.0)	
		Median Time (months) [a]	6.6	3.1	
		95% CI	(3.3, 14.4)	(1.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.1722
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.703
		95% CI for Hazard Ratio			(0.422, 1.172)
		P-value of Subgroup*Treatment Interaction [d]			0.8640
Insomnia	Europe	Number of Patients	94	97	
		Patients With Events (%)	42 (44.7)	45 (46.4)	
		Patients Without Events (Censored) (%)	52 (55.3)	52 (53.6)	
		Median Time (months) [a]	6.0	3.9	
		95% CI	(4.7, 18.9)	(2.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.1671
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.745
		95% CI for Hazard Ratio			(0.487, 1.138)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	North America	Number of Patients	66	53	
		Patients With Events (%)	26 (39.4)	24 (45.3)	
		Patients Without Events (Censored) (%)	40 (60.6)	29 (54.7)	
		Median Time (months) [a]	8.7	3.1	
		95% CI	(6.3, NE)	(2.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.0445
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.565
		95% CI for Hazard Ratio			(0.320, 0.997)
		P-value of Subgroup*Treatment Interaction [d]			0.4953
Appetite Loss	Europe	Number of Patients	101	101	
		Patients With Events (%)	60 (59.4)	45 (44.6)	
		Patients Without Events (Censored) (%)	41 (40.6)	56 (55.4)	
		Median Time (months) [a]	4.4	5.3	
		95% CI	(1.7, 6.0)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.2348
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.264
		95% CI for Hazard Ratio			(0.855, 1.868)
	North America	Number of Patients	66	55	
		Patients With Events (%)	37 (56.1)	33 (60.0)	
		Patients Without Events (Censored) (%)	29 (43.9)	22 (40.0)	
		Median Time (months) [a]	3.3	3.1	
		95% CI	(1.7, 7.4)	(1.2, 4.7)	
		Log-rank p-value (Unstratified) [b]			0.3329
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.794
		95% CI for Hazard Ratio			(0.496, 1.271)
		P-value of Subgroup*Treatment Interaction [d]			0.1096

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Europe	Number of Patients	102	103	
		Patients With Events (%)	46 (45.1)	46 (44.7)	
		Patients Without Events (Censored) (%)	56 (54.9)	57 (55.3)	
		Median Time (months) [a]	5.6	4.9	
		95% CI	(3.2, NE)	(3.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.8756
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.968
		95% CI for Hazard Ratio			(0.643, 1.458)
	North America	Number of Patients	68	55	
		Patients With Events (%)	37 (54.4)	24 (43.6)	
		Patients Without Events (Censored) (%)	31 (45.6)	31 (56.4)	
		Median Time (months) [a]	4.6	4.2	
		95% CI	(1.6, 13.9)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.7717
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.079
		95% CI for Hazard Ratio			(0.644, 1.807)
		P-value of Subgroup*Treatment Interaction [d]			0.7252
Diarrhea	Europe	Number of Patients	105	105	
		Patients With Events (%)	70 (66.7)	39 (37.1)	
		Patients Without Events (Censored) (%)	35 (33.3)	66 (62.9)	
		Median Time (months) [a]	1.7	7.7	
		95% CI	(1.4, 2.4)	(5.3, 10.9)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.595
		95% CI for Hazard Ratio			(1.746, 3.857)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	North America	Number of Patients	67	59	
		Patients With Events (%)	34 (50.7)	16 (27.1)	
		Patients Without Events (Censored) (%)	33 (49.3)	43 (72.9)	
		Median Time (months) [a]	4.0	NE	
		95% CI	(1.7, 16.5)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.0288
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.919
		95% CI for Hazard Ratio			(1.056, 3.489)
		P-value of Subgroup*Treatment Interaction [d]			0.4289
Financial Difficulties	Europe	Number of Patients	102	102	
		Patients With Events (%)	25 (24.5)	21 (20.6)	
		Patients Without Events (Censored) (%)	77 (75.5)	81 (79.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(8.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.9351
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.025
		95% CI for Hazard Ratio			(0.571, 1.838)
	North America	Number of Patients	67	57	
		Patients With Events (%)	18 (26.9)	10 (17.5)	
		Patients Without Events (Censored) (%)	49 (73.1)	47 (82.5)	
		Median Time (months) [a]	NE	NE	
		95% CI	(7.2, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.5186
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.289
		95% CI for Hazard Ratio			(0.594, 2.797)
		P-value of Subgroup*Treatment Interaction [d]			0.6743

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.7
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Geographic region
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Europe	Number of Patients	106	106	
		Patients With Events (%)	55 (51.9)	47 (44.3)	
		Patients Without Events (Censored) (%)	51 (48.1)	59 (55.7)	
		Median Time (months) [a]	5.1	6.4	
		95% CI	(2.9, 7.5)	(3.7, 10.3)	
		Log-rank p-value (Unstratified) [b]			0.6181
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.103
		95% CI for Hazard Ratio			(0.747, 1.629)
	North America	Number of Patients	68	59	
		Patients With Events (%)	30 (44.1)	32 (54.2)	
		Patients Without Events (Censored) (%)	38 (55.9)	27 (45.8)	
		Median Time (months) [a]	8.3	3.1	
		95% CI	(3.7, 23.6)	(2.1, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.0475
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.604
		95% CI for Hazard Ratio			(0.364, 1.002)
		P-value of Subgroup*Treatment Interaction [d]			0.0455

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	≤ 12 Months	Number of Patients	97	99	
		Patients With Events (%)	51 (52.6)	60 (60.6)	
		Patients Without Events (Censored) (%)	46 (47.4)	39 (39.4)	
		Median Time (months) [a]	5.6	2.9	
		95% CI	(3.2, 9.4)	(1.8, 3.9)	
		Log-rank p-value (Unstratified) [b]			0.0027
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.560
		95% CI for Hazard Ratio			(0.381, 0.824)
	> 12 Months	Number of Patients	73	63	
		Patients With Events (%)	44 (60.3)	42 (66.7)	
		Patients Without Events (Censored) (%)	29 (39.7)	21 (33.3)	
		Median Time (months) [a]	3.0	2.6	
		95% CI	(1.5, 6.1)	(1.4, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.5256
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.873
		95% CI for Hazard Ratio			(0.572, 1.333)
		P-value of Subgroup*Treatment Interaction [d]			0.1714
Physical Functioning	≤ 12 Months	Number of Patients	98	99	
		Patients With Events (%)	50 (51.0)	53 (53.5)	
		Patients Without Events (Censored) (%)	48 (49.0)	46 (46.5)	
		Median Time (months) [a]	6.1	3.5	
		95% CI	(3.3, 10.3)	(2.1, 6.0)	
		Log-rank p-value (Unstratified) [b]			0.0288
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.650
		95% CI for Hazard Ratio			(0.440, 0.961)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	> 12 Months	Number of Patients	73	63	
		Patients With Events (%)	37 (50.7)	33 (52.4)	
		Patients Without Events (Censored) (%)	36 (49.3)	30 (47.6)	
		Median Time (months) [a]	4.2	3.4	
		95% CI	(1.7, NE)	(2.2, 7.7)	
		Log-rank p-value (Unstratified) [b]			0.6860
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.908
		95% CI for Hazard Ratio			(0.567, 1.453)
		P-value of Subgroup*Treatment Interaction [d]			0.3693
Role Functioning	≤ 12 Months	Number of Patients	95	95	
		Patients With Events (%)	65 (68.4)	59 (62.1)	
		Patients Without Events (Censored) (%)	30 (31.6)	36 (37.9)	
		Median Time (months) [a]	2.9	2.0	
		95% CI	(1.7, 4.5)	(1.4, 3.1)	
		Log-rank p-value (Unstratified) [b]			0.1824
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.786
		95% CI for Hazard Ratio			(0.549, 1.125)
	> 12 Months	Number of Patients	73	62	
		Patients With Events (%)	45 (61.6)	42 (67.7)	
		Patients Without Events (Censored) (%)	28 (38.4)	20 (32.3)	
		Median Time (months) [a]	2.1	2.7	
		95% CI	(1.7, 4.6)	(1.4, 3.4)	
		Log-rank p-value (Unstratified) [b]			0.3268
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.812
		95% CI for Hazard Ratio			(0.533, 1.238)
		P-value of Subgroup*Treatment Interaction [d]			0.9642

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	≤ 12 Months	Number of Patients	96	99	
		Patients With Events (%)	34 (35.4)	51 (51.5)	
		Patients Without Events (Censored) (%)	62 (64.6)	48 (48.5)	
		Median Time (months) [a]	12.8	3.5	
		95% CI	(7.2, NE)	(2.1, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.0014
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.498
		95% CI for Hazard Ratio			(0.322, 0.771)
	> 12 Months	Number of Patients	70	63	
		Patients With Events (%)	27 (38.6)	23 (36.5)	
		Patients Without Events (Censored) (%)	43 (61.4)	40 (63.5)	
		Median Time (months) [a]	NE	9.5	
		95% CI	(3.2, NE)	(4.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.8271
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.064
		95% CI for Hazard Ratio			(0.610, 1.856)
		P-value of Subgroup*Treatment Interaction [d]			0.0331
Cognitive Functioning	≤ 12 Months	Number of Patients	98	100	
		Patients With Events (%)	47 (48.0)	43 (43.0)	
		Patients Without Events (Censored) (%)	51 (52.0)	57 (57.0)	
		Median Time (months) [a]	6.0	4.9	
		95% CI	(3.7, 15.2)	(3.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.3440
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.818
		95% CI for Hazard Ratio			(0.537, 1.244)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	> 12 Months	Number of Patients	73	62	
		Patients With Events (%)	37 (50.7)	22 (35.5)	
		Patients Without Events (Censored) (%)	36 (49.3)	40 (64.5)	
		Median Time (months) [a]	3.2	10.6	
		95% CI	(2.1, 18.2)	(3.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.1373
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.489
		95% CI for Hazard Ratio			(0.876, 2.532)
		P-value of Subgroup*Treatment Interaction [d]			0.0989
Social Functioning	≤ 12 Months	Number of Patients	98	96	
		Patients With Events (%)	56 (57.1)	54 (56.3)	
		Patients Without Events (Censored) (%)	42 (42.9)	42 (43.8)	
		Median Time (months) [a]	4.0	3.6	
		95% CI	(2.3, 6.7)	(2.3, 4.4)	
		Log-rank p-value (Unstratified) [b]			0.2722
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.811
		95% CI for Hazard Ratio			(0.556, 1.183)
	> 12 Months	Number of Patients	69	59	
		Patients With Events (%)	44 (63.8)	33 (55.9)	
		Patients Without Events (Censored) (%)	25 (36.2)	26 (44.1)	
		Median Time (months) [a]	1.7	2.9	
		95% CI	(1.2, 2.8)	(2.1, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.1871
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.351
		95% CI for Hazard Ratio			(0.858, 2.125)
		P-value of Subgroup*Treatment Interaction [d]			0.1563

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	≤ 12 Months	Number of Patients	97	97	
		Patients With Events (%)	68 (70.1)	77 (79.4)	
		Patients Without Events (Censored) (%)	29 (29.9)	20 (20.6)	
		Median Time (months) [a]	2.0	1.0	
		95% CI	(1.4, 3.9)	(0.9, 1.5)	
		Log-rank p-value (Unstratified) [b]			0.0018
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.595
		95% CI for Hazard Ratio			(0.425, 0.831)
	> 12 Months	Number of Patients	72	63	
		Patients With Events (%)	51 (70.8)	45 (71.4)	
		Patients Without Events (Censored) (%)	21 (29.2)	18 (28.6)	
		Median Time (months) [a]	2.1	1.6	
		95% CI	(1.4, 3.0)	(1.0, 2.1)	
		Log-rank p-value (Unstratified) [b]			0.3212
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.818
		95% CI for Hazard Ratio			(0.546, 1.224)
		P-value of Subgroup*Treatment Interaction [d]			0.3106
Nausea and Vomiting	≤ 12 Months	Number of Patients	98	100	
		Patients With Events (%)	61 (62.2)	52 (52.0)	
		Patients Without Events (Censored) (%)	37 (37.8)	48 (48.0)	
		Median Time (months) [a]	2.4	3.5	
		95% CI	(1.5, 4.1)	(2.1, 7.2)	
		Log-rank p-value (Unstratified) [b]			0.6995
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.075
		95% CI for Hazard Ratio			(0.740, 1.562)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	> 12 Months	Number of Patients	72	63	
		Patients With Events (%)	42 (58.3)	24 (38.1)	
		Patients Without Events (Censored) (%)	30 (41.7)	39 (61.9)	
		Median Time (months) [a]	2.6	9.5	
		95% CI	(1.5, 4.9)	(3.5, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.0898
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.539
		95% CI for Hazard Ratio			(0.928, 2.552)
		P-value of Subgroup*Treatment Interaction [d]			0.2545
Pain	≤ 12 Months	Number of Patients	96	94	
		Patients With Events (%)	54 (56.3)	55 (58.5)	
		Patients Without Events (Censored) (%)	42 (43.8)	39 (41.5)	
		Median Time (months) [a]	5.0	3.1	
		95% CI	(2.8, 6.7)	(1.4, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.1155
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.739
		95% CI for Hazard Ratio			(0.504, 1.082)
	> 12 Months	Number of Patients	71	63	
		Patients With Events (%)	40 (56.3)	35 (55.6)	
		Patients Without Events (Censored) (%)	31 (43.7)	28 (44.4)	
		Median Time (months) [a]	3.7	3.3	
		95% CI	(1.9, 6.1)	(2.2, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.7683
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.934
		95% CI for Hazard Ratio			(0.593, 1.471)
		P-value of Subgroup*Treatment Interaction [d]			0.4638

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	≤ 12 Months	Number of Patients	95	96	
		Patients With Events (%)	43 (45.3)	52 (54.2)	
		Patients Without Events (Censored) (%)	52 (54.7)	44 (45.8)	
		Median Time (months) [a]	5.8	3.5	
		95% CI	(3.4, NE)	(1.9, 7.5)	
		Log-rank p-value (Unstratified) [b]			0.0277
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.638
		95% CI for Hazard Ratio			(0.425, 0.958)
	> 12 Months	Number of Patients	72	63	
		Patients With Events (%)	35 (48.6)	30 (47.6)	
		Patients Without Events (Censored) (%)	37 (51.4)	33 (52.4)	
		Median Time (months) [a]	6.7	5.1	
		95% CI	(3.3, 14.4)	(2.2, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.5321
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.855
		95% CI for Hazard Ratio			(0.521, 1.402)
		P-value of Subgroup*Treatment Interaction [d]			0.2119
Insomnia	≤ 12 Months	Number of Patients	88	89	
		Patients With Events (%)	41 (46.6)	43 (48.3)	
		Patients Without Events (Censored) (%)	47 (53.4)	46 (51.7)	
		Median Time (months) [a]	6.0	3.2	
		95% CI	(4.2, 18.9)	(1.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.0404
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.638
		95% CI for Hazard Ratio			(0.411, 0.989)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	> 12 Months	Number of Patients	71	59	
		Patients With Events (%)	27 (38.0)	25 (42.4)	
		Patients Without Events (Censored) (%)	44 (62.0)	34 (57.6)	
		Median Time (months) [a]	18.2	4.4	
		95% CI	(6.3, NE)	(2.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.2604
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.731
		95% CI for Hazard Ratio			(0.421, 1.269)
		P-value of Subgroup*Treatment Interaction [d]			0.6945
Appetite Loss	≤ 12 Months	Number of Patients	93	96	
		Patients With Events (%)	53 (57.0)	50 (52.1)	
		Patients Without Events (Censored) (%)	40 (43.0)	46 (47.9)	
		Median Time (months) [a]	5.5	3.1	
		95% CI	(1.7, 9.1)	(2.1, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.4680
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.865
		95% CI for Hazard Ratio			(0.583, 1.284)
	> 12 Months	Number of Patients	71	59	
		Patients With Events (%)	43 (60.6)	27 (45.8)	
		Patients Without Events (Censored) (%)	28 (39.4)	32 (54.2)	
		Median Time (months) [a]	2.8	5.6	
		95% CI	(1.5, 4.9)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.1273
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.448
		95% CI for Hazard Ratio			(0.894, 2.345)
		P-value of Subgroup*Treatment Interaction [d]			0.1650

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	≤ 12 Months	Number of Patients	97	95	
		Patients With Events (%)	46 (47.4)	44 (46.3)	
		Patients Without Events (Censored) (%)	51 (52.6)	51 (53.7)	
		Median Time (months) [a]	5.0	4.2	
		95% CI	(2.8, NE)	(3.1, 6.7)	
		Log-rank p-value (Unstratified) [b]			0.5157
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.871
		95% CI for Hazard Ratio			(0.574, 1.323)
	> 12 Months	Number of Patients	70	61	
		Patients With Events (%)	36 (51.4)	25 (41.0)	
		Patients Without Events (Censored) (%)	34 (48.6)	36 (59.0)	
		Median Time (months) [a]	5.4	4.9	
		95% CI	(2.0, 14.4)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.3159
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.296
		95% CI for Hazard Ratio			(0.777, 2.159)
		P-value of Subgroup*Treatment Interaction [d]			0.2495
Diarrhea	≤ 12 Months	Number of Patients	97	99	
		Patients With Events (%)	60 (61.9)	31 (31.3)	
		Patients Without Events (Censored) (%)	37 (38.1)	68 (68.7)	
		Median Time (months) [a]	2.0	7.7	
		95% CI	(1.5, 3.4)	(5.3, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.406
		95% CI for Hazard Ratio			(1.557, 3.716)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	> 12 Months	Number of Patients	72	63	
		Patients With Events (%)	43 (59.7)	24 (38.1)	
		Patients Without Events (Censored) (%)	29 (40.3)	39 (61.9)	
		Median Time (months) [a]	1.9	9.8	
		95% CI	(1.5, 5.6)	(5.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0036
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.063
		95% CI for Hazard Ratio			(1.247, 3.412)
		P-value of Subgroup*Treatment Interaction [d]			0.6317
Financial Difficulties	≤ 12 Months	Number of Patients	95	97	
		Patients With Events (%)	20 (21.1)	25 (25.8)	
		Patients Without Events (Censored) (%)	75 (78.9)	72 (74.2)	
		Median Time (months) [a]	NE	NE	
		95% CI	(NE, NE)	(6.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.0990
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.611
		95% CI for Hazard Ratio			(0.338, 1.104)
	> 12 Months	Number of Patients	71	61	
		Patients With Events (%)	23 (32.4)	6 (9.8)	
		Patients Without Events (Censored) (%)	48 (67.6)	55 (90.2)	
		Median Time (months) [a]	18.2	NE	
		95% CI	(5.4, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.0035
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			3.498
		95% CI for Hazard Ratio			(1.421, 8.610)
		P-value of Subgroup*Treatment Interaction [d]			0.0013

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.8
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Prior CDK inhibitor treatment duration
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	≤ 12 Months	Number of Patients	98	100	
		Patients With Events (%)	45 (45.9)	50 (50.0)	
		Patients Without Events (Censored) (%)	53 (54.1)	50 (50.0)	
		Median Time (months) [a]	6.7	4.4	
		95% CI	(3.9, NE)	(3.0, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.0954
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.711
		95% CI for Hazard Ratio			(0.474, 1.066)
	> 12 Months	Number of Patients	73	63	
		Patients With Events (%)	40 (54.8)	28 (44.4)	
		Patients Without Events (Censored) (%)	33 (45.2)	35 (55.6)	
		Median Time (months) [a]	4.9	8.2	
		95% CI	(2.1, 8.3)	(2.9, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.4580
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.201
		95% CI for Hazard Ratio			(0.738, 1.953)
		P-value of Subgroup*Treatment Interaction [d]			0.0966

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Yes	Number of Patients	12	9	
		Patients With Events (%)	6 (50.0)	3 (33.3)	
		Patients Without Events (Censored) (%)	6 (50.0)	6 (66.7)	
		Median Time (months) [a]	6.1	NE	
		95% CI	(0.7, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.7605
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.249
		95% CI for Hazard Ratio			(0.296, 5.276)
	No	Number of Patients	154	152	
		Patients With Events (%)	84 (54.5)	98 (64.5)	
		Patients Without Events (Censored) (%)	70 (45.5)	54 (35.5)	
		Median Time (months) [a]	4.9	2.5	
		95% CI	(2.9, 6.7)	(1.9, 3.3)	
		Log-rank p-value (Unstratified) [b]			0.0045
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.657
		95% CI for Hazard Ratio			(0.490, 0.881)
		P-value of Subgroup*Treatment Interaction [d]			0.4726
Physical Functioning	Yes	Number of Patients	12	9	
		Patients With Events (%)	5 (41.7)	3 (33.3)	
		Patients Without Events (Censored) (%)	7 (58.3)	6 (66.7)	
		Median Time (months) [a]	7.1	NE	
		95% CI	(1.7, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.5327
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.616
		95% CI for Hazard Ratio			(0.133, 2.856)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	155	152	
		Patients With Events (%)	78 (50.3)	81 (53.3)	
		Patients Without Events (Censored) (%)	77 (49.7)	71 (46.7)	
		Median Time (months) [a]	5.6	3.4	
		95% CI	(3.0, 8.3)	(2.2, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.0887
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.764
		95% CI for Hazard Ratio			(0.559, 1.045)
		P-value of Subgroup*Treatment Interaction [d]			0.9564
Role Functioning	Yes	Number of Patients	12	9	
		Patients With Events (%)	8 (66.7)	6 (66.7)	
		Patients Without Events (Censored) (%)	4 (33.3)	3 (33.3)	
		Median Time (months) [a]	2.2	1.4	
		95% CI	(0.7, NE)	(0.8, 2.8)	
		Log-rank p-value (Unstratified) [b]			0.5826
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.732
		95% CI for Hazard Ratio			(0.236, 2.265)
	No	Number of Patients	152	147	
		Patients With Events (%)	96 (63.2)	94 (63.9)	
		Patients Without Events (Censored) (%)	56 (36.8)	53 (36.1)	
		Median Time (months) [a]	2.9	2.2	
		95% CI	(1.7, 4.5)	(1.4, 3.1)	
		Log-rank p-value (Unstratified) [b]			0.0861
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.781
		95% CI for Hazard Ratio			(0.587, 1.040)
		P-value of Subgroup*Treatment Interaction [d]			0.7487

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Yes	Number of Patients	12	9	
		Patients With Events (%)	4 (33.3)	4 (44.4)	
		Patients Without Events (Censored) (%)	8 (66.7)	5 (55.6)	
		Median Time (months) [a]	8.9	1.8	
		95% CI	(2.4, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.1139
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.272
		95% CI for Hazard Ratio			(0.049, 1.520)
	No	Number of Patients	150	152	
		Patients With Events (%)	52 (34.7)	69 (45.4)	
		Patients Without Events (Censored) (%)	98 (65.3)	83 (54.6)	
		Median Time (months) [a]	NE	4.5	
		95% CI	(6.5, NE)	(3.4, 10.6)	
		Log-rank p-value (Unstratified) [b]			0.0133
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.638
		95% CI for Hazard Ratio			(0.444, 0.915)
		P-value of Subgroup*Treatment Interaction [d]			0.6674
Cognitive Functioning	Yes	Number of Patients	12	9	
		Patients With Events (%)	6 (50.0)	5 (55.6)	
		Patients Without Events (Censored) (%)	6 (50.0)	4 (44.4)	
		Median Time (months) [a]	7.6	1.4	
		95% CI	(1.1, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.1570
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.405
		95% CI for Hazard Ratio			(0.112, 1.470)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	155	152	
		Patients With Events (%)	73 (47.1)	60 (39.5)	
		Patients Without Events (Censored) (%)	82 (52.9)	92 (60.5)	
		Median Time (months) [a]	5.2	7.2	
		95% CI	(3.2, 18.2)	(4.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.7932
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.047
		95% CI for Hazard Ratio			(0.742, 1.478)
		P-value of Subgroup*Treatment Interaction [d]			0.1842
Social Functioning	Yes	Number of Patients	12	9	
		Patients With Events (%)	5 (41.7)	4 (44.4)	
		Patients Without Events (Censored) (%)	7 (58.3)	5 (55.6)	
		Median Time (months) [a]	8.2	NE	
		95% CI	(1.6, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.3403
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.513
		95% CI for Hazard Ratio			(0.127, 2.072)
	No	Number of Patients	151	145	
		Patients With Events (%)	89 (58.9)	82 (56.6)	
		Patients Without Events (Censored) (%)	62 (41.1)	63 (43.4)	
		Median Time (months) [a]	2.3	3.1	
		95% CI	(1.7, 4.3)	(2.4, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.9975
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.000
		95% CI for Hazard Ratio			(0.740, 1.352)
		P-value of Subgroup*Treatment Interaction [d]			0.4688

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Yes	Number of Patients	12	9	
		Patients With Events (%)	8 (66.7)	8 (88.9)	
		Patients Without Events (Censored) (%)	4 (33.3)	1 (11.1)	
		Median Time (months) [a]	1.7	0.9	
		95% CI	(0.7, NE)	(0.7, 1.8)	
		Log-rank p-value (Unstratified) [b]			0.1783
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.520
		95% CI for Hazard Ratio			(0.192, 1.411)
	No	Number of Patients	153	150	
		Patients With Events (%)	108 (70.6)	113 (75.3)	
		Patients Without Events (Censored) (%)	45 (29.4)	37 (24.7)	
		Median Time (months) [a]	2.2	1.3	
		95% CI	(1.5, 2.9)	(1.0, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0064
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.695
		95% CI for Hazard Ratio			(0.533, 0.908)
		P-value of Subgroup*Treatment Interaction [d]			0.4452
Nausea and Vomiting	Yes	Number of Patients	12	9	
		Patients With Events (%)	6 (50.0)	4 (44.4)	
		Patients Without Events (Censored) (%)	6 (50.0)	5 (55.6)	
		Median Time (months) [a]	NE	NE	
		95% CI	(0.7, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.7041
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.778
		95% CI for Hazard Ratio			(0.211, 2.866)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	154	153	
		Patients With Events (%)	96 (62.3)	70 (45.8)	
		Patients Without Events (Censored) (%)	58 (37.7)	83 (54.2)	
		Median Time (months) [a]	2.1	6.1	
		95% CI	(1.5, 3.9)	(2.9, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.0501
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.357
		95% CI for Hazard Ratio			(0.995, 1.850)
		P-value of Subgroup*Treatment Interaction [d]			0.3398
Pain	Yes	Number of Patients	11	9	
		Patients With Events (%)	5 (45.5)	4 (44.4)	
		Patients Without Events (Censored) (%)	6 (54.5)	5 (55.6)	
		Median Time (months) [a]	6.1	2.3	
		95% CI	(0.7, NE)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.8488
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.873
		95% CI for Hazard Ratio			(0.216, 3.524)
	No	Number of Patients	151	147	
		Patients With Events (%)	84 (55.6)	85 (57.8)	
		Patients Without Events (Censored) (%)	67 (44.4)	62 (42.2)	
		Median Time (months) [a]	4.0	3.1	
		95% CI	(2.8, 6.1)	(2.2, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.1439
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.800
		95% CI for Hazard Ratio			(0.591, 1.083)
		P-value of Subgroup*Treatment Interaction [d]			0.9573

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Yes	Number of Patients	12	8	
		Patients With Events (%)	4 (33.3)	2 (25.0)	
		Patients Without Events (Censored) (%)	8 (66.7)	6 (75.0)	
		Median Time (months) [a]	NE	NE	
		95% CI	(0.9, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.9848
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.983
		95% CI for Hazard Ratio			(0.174, 5.557)
	No	Number of Patients	151	150	
		Patients With Events (%)	71 (47.0)	80 (53.3)	
		Patients Without Events (Censored) (%)	80 (53.0)	70 (46.7)	
		Median Time (months) [a]	6.6	3.9	
		95% CI	(4.3, 9.5)	(2.4, 7.5)	
		Log-rank p-value (Unstratified) [b]			0.0284
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.699
		95% CI for Hazard Ratio			(0.506, 0.966)
		P-value of Subgroup*Treatment Interaction [d]			0.9230
Insomnia	Yes	Number of Patients	11	7	
		Patients With Events (%)	7 (63.6)	5 (71.4)	
		Patients Without Events (Censored) (%)	4 (36.4)	2 (28.6)	
		Median Time (months) [a]	3.7	1.4	
		95% CI	(0.7, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.2325
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.458
		95% CI for Hazard Ratio			(0.122, 1.728)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	142	141	
		Patients With Events (%)	57 (40.1)	63 (44.7)	
		Patients Without Events (Censored) (%)	85 (59.9)	78 (55.3)	
		Median Time (months) [a]	8.7	3.9	
		95% CI	(6.0, NE)	(2.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.0294
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.672
		95% CI for Hazard Ratio			(0.468, 0.966)
		P-value of Subgroup*Treatment Interaction [d]			0.5432
Appetite Loss	Yes	Number of Patients	11	9	
		Patients With Events (%)	6 (54.5)	4 (44.4)	
		Patients Without Events (Censored) (%)	5 (45.5)	5 (55.6)	
		Median Time (months) [a]	0.9	3.7	
		95% CI	(0.7, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.5988
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.392
		95% CI for Hazard Ratio			(0.392, 4.948)
	No	Number of Patients	150	144	
		Patients With Events (%)	85 (56.7)	72 (50.0)	
		Patients Without Events (Censored) (%)	65 (43.3)	72 (50.0)	
		Median Time (months) [a]	4.3	3.7	
		95% CI	(1.8, 6.0)	(2.2, 5.6)	
		Log-rank p-value (Unstratified) [b]			0.8773
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.025
		95% CI for Hazard Ratio			(0.748, 1.405)
		P-value of Subgroup*Treatment Interaction [d]			0.8329

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Yes	Number of Patients	12	9	
		Patients With Events (%)	7 (58.3)	7 (77.8)	
		Patients Without Events (Censored) (%)	5 (41.7)	2 (22.2)	
		Median Time (months) [a]	5.8	1.5	
		95% CI	(0.8, NE)	(0.7, 3.1)	
		Log-rank p-value (Unstratified) [b]			0.1279
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.435
		95% CI for Hazard Ratio			(0.144, 1.320)
	No	Number of Patients	151	146	
		Patients With Events (%)	72 (47.7)	62 (42.5)	
		Patients Without Events (Censored) (%)	79 (52.3)	84 (57.5)	
		Median Time (months) [a]	5.4	4.9	
		95% CI	(3.2, 14.4)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.7103
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.066
		95% CI for Hazard Ratio			(0.759, 1.498)
		P-value of Subgroup*Treatment Interaction [d]			0.1281
Diarrhea	Yes	Number of Patients	12	9	
		Patients With Events (%)	5 (41.7)	3 (33.3)	
		Patients Without Events (Censored) (%)	7 (58.3)	6 (66.7)	
		Median Time (months) [a]	NE	3.5	
		95% CI	(0.7, NE)	(0.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.9855
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.987
		95% CI for Hazard Ratio			(0.228, 4.262)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	154	152	
		Patients With Events (%)	95 (61.7)	52 (34.2)	
		Patients Without Events (Censored) (%)	59 (38.3)	100 (65.8)	
		Median Time (months) [a]	1.9	8.2	
		95% CI	(1.5, 3.2)	(5.8, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.355
		95% CI for Hazard Ratio			(1.677, 3.307)
		P-value of Subgroup*Treatment Interaction [d]			0.1980
Financial Difficulties	Yes	Number of Patients	12	9	
		Patients With Events (%)	3 (25.0)	2 (22.2)	
		Patients Without Events (Censored) (%)	9 (75.0)	7 (77.8)	
		Median Time (months) [a]	NE	NE	
		95% CI	(1.1, NE)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.8243
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.813
		95% CI for Hazard Ratio			(0.131, 5.064)
	No	Number of Patients	150	148	
		Patients With Events (%)	38 (25.3)	29 (19.6)	
		Patients Without Events (Censored) (%)	112 (74.7)	119 (80.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.5832
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.145
		95% CI for Hazard Ratio			(0.705, 1.861)
		P-value of Subgroup*Treatment Interaction [d]			0.5084

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.9
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Early relapse
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Yes	Number of Patients	12	9	
		Patients With Events (%)	6 (50.0)	3 (33.3)	
		Patients Without Events (Censored) (%)	6 (50.0)	6 (66.7)	
		Median Time (months) [a]	NE	NE	
		95% CI	(0.7, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.6830
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.337
		95% CI for Hazard Ratio			(0.328, 5.454)
	No	Number of Patients	155	153	
		Patients With Events (%)	74 (47.7)	74 (48.4)	
		Patients Without Events (Censored) (%)	81 (52.3)	79 (51.6)	
		Median Time (months) [a]	5.9	4.9	
		95% CI	(4.2, 9.2)	(3.1, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.2419
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.825
		95% CI for Hazard Ratio			(0.597, 1.141)
		P-value of Subgroup*Treatment Interaction [d]			0.6951

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Yes	Number of Patients	102	107	
		Patients With Events (%)	56 (54.9)	67 (62.6)	
		Patients Without Events (Censored) (%)	46 (45.1)	40 (37.4)	
		Median Time (months) [a]	5.6	2.6	
		95% CI	(3.7, 8.0)	(1.5, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.0071
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.614
		95% CI for Hazard Ratio			(0.428, 0.881)
	No	Number of Patients	71	57	
		Patients With Events (%)	39 (54.9)	36 (63.2)	
		Patients Without Events (Censored) (%)	32 (45.1)	21 (36.8)	
		Median Time (months) [a]	2.9	2.8	
		95% CI	(1.6, 9.1)	(1.9, 3.9)	
		Log-rank p-value (Unstratified) [b]			0.2749
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.778
		95% CI for Hazard Ratio			(0.494, 1.225)
		P-value of Subgroup*Treatment Interaction [d]			0.4932
Physical Functioning	Yes	Number of Patients	103	106	
		Patients With Events (%)	54 (52.4)	56 (52.8)	
		Patients Without Events (Censored) (%)	49 (47.6)	50 (47.2)	
		Median Time (months) [a]	5.5	3.5	
		95% CI	(3.0, 8.3)	(2.7, 6.2)	
		Log-rank p-value (Unstratified) [b]			0.2264
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.794
		95% CI for Hazard Ratio			(0.545, 1.157)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	71	58	
		Patients With Events (%)	34 (47.9)	31 (53.4)	
		Patients Without Events (Censored) (%)	37 (52.1)	27 (46.6)	
		Median Time (months) [a]	5.6	2.2	
		95% CI	(2.3, NE)	(1.9, 7.3)	
		Log-rank p-value (Unstratified) [b]			0.1077
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.672
		95% CI for Hazard Ratio			(0.411, 1.099)
		P-value of Subgroup*Treatment Interaction [d]			0.4411
Role Functioning	Yes	Number of Patients	102	104	
		Patients With Events (%)	68 (66.7)	73 (70.2)	
		Patients Without Events (Censored) (%)	34 (33.3)	31 (29.8)	
		Median Time (months) [a]	2.8	1.9	
		95% CI	(1.7, 4.5)	(1.4, 2.8)	
		Log-rank p-value (Unstratified) [b]			0.0155
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.664
		95% CI for Hazard Ratio			(0.474, 0.930)
	No	Number of Patients	69	55	
		Patients With Events (%)	43 (62.3)	29 (52.7)	
		Patients Without Events (Censored) (%)	26 (37.7)	26 (47.3)	
		Median Time (months) [a]	2.3	4.3	
		95% CI	(1.5, 5.0)	(1.4, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.7532
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.077
		95% CI for Hazard Ratio			(0.673, 1.726)
		P-value of Subgroup*Treatment Interaction [d]			0.1432

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Yes	Number of Patients	100	106	
		Patients With Events (%)	36 (36.0)	54 (50.9)	
		Patients Without Events (Censored) (%)	64 (64.0)	52 (49.1)	
		Median Time (months) [a]	NE	4.2	
		95% CI	(5.5, NE)	(3.1, 5.3)	
		Log-rank p-value (Unstratified) [b]			0.0062
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.559
		95% CI for Hazard Ratio			(0.366, 0.854)
	No	Number of Patients	69	58	
		Patients With Events (%)	25 (36.2)	21 (36.2)	
		Patients Without Events (Censored) (%)	44 (63.8)	37 (63.8)	
		Median Time (months) [a]	12.8	10.6	
		95% CI	(4.2, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.6223
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.865
		95% CI for Hazard Ratio			(0.484, 1.546)
		P-value of Subgroup*Treatment Interaction [d]			0.2336
Cognitive Functioning	Yes	Number of Patients	103	107	
		Patients With Events (%)	52 (50.5)	49 (45.8)	
		Patients Without Events (Censored) (%)	51 (49.5)	58 (54.2)	
		Median Time (months) [a]	5.2	4.3	
		95% CI	(2.5, 11.1)	(3.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.8091
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.953
		95% CI for Hazard Ratio			(0.644, 1.411)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	71	57	
		Patients With Events (%)	34 (47.9)	18 (31.6)	
		Patients Without Events (Censored) (%)	37 (52.1)	39 (68.4)	
		Median Time (months) [a]	5.0	10.6	
		95% CI	(2.8, 18.8)	(4.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.3889
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.287
		95% CI for Hazard Ratio			(0.722, 2.296)
		P-value of Subgroup*Treatment Interaction [d]			0.3219
Social Functioning	Yes	Number of Patients	101	101	
		Patients With Events (%)	61 (60.4)	61 (60.4)	
		Patients Without Events (Censored) (%)	40 (39.6)	40 (39.6)	
		Median Time (months) [a]	2.4	3.1	
		95% CI	(1.7, 4.3)	(2.4, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.6731
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.926
		95% CI for Hazard Ratio			(0.647, 1.326)
	No	Number of Patients	69	56	
		Patients With Events (%)	40 (58.0)	27 (48.2)	
		Patients Without Events (Censored) (%)	29 (42.0)	29 (51.8)	
		Median Time (months) [a]	2.4	3.6	
		95% CI	(1.4, 8.1)	(1.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.6510
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.118
		95% CI for Hazard Ratio			(0.685, 1.824)
		P-value of Subgroup*Treatment Interaction [d]			0.6943

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Yes	Number of Patients	102	105	
		Patients With Events (%)	73 (71.6)	83 (79.0)	
		Patients Without Events (Censored) (%)	29 (28.4)	22 (21.0)	
		Median Time (months) [a]	1.9	1.3	
		95% CI	(1.5, 2.6)	(1.0, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0244
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.698
		95% CI for Hazard Ratio			(0.508, 0.961)
	No	Number of Patients	70	57	
		Patients With Events (%)	48 (68.6)	41 (71.9)	
		Patients Without Events (Censored) (%)	22 (31.4)	16 (28.1)	
		Median Time (months) [a]	2.4	1.1	
		95% CI	(1.2, 3.9)	(0.9, 2.1)	
		Log-rank p-value (Unstratified) [b]			0.0813
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.694
		95% CI for Hazard Ratio			(0.455, 1.058)
		P-value of Subgroup*Treatment Interaction [d]			0.9586
Nausea and Vomiting	Yes	Number of Patients	102	107	
		Patients With Events (%)	61 (59.8)	53 (49.5)	
		Patients Without Events (Censored) (%)	41 (40.2)	54 (50.5)	
		Median Time (months) [a]	2.6	3.7	
		95% CI	(1.5, 5.6)	(2.8, 7.4)	
		Log-rank p-value (Unstratified) [b]			0.6534
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.088
		95% CI for Hazard Ratio			(0.749, 1.581)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	71	58	
		Patients With Events (%)	45 (63.4)	24 (41.4)	
		Patients Without Events (Censored) (%)	26 (36.6)	34 (58.6)	
		Median Time (months) [a]	2.0	9.6	
		95% CI	(1.4, 4.1)	(2.3, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.0394
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.664
		95% CI for Hazard Ratio			(1.011, 2.737)
		P-value of Subgroup*Treatment Interaction [d]			0.1696
Pain	Yes	Number of Patients	98	102	
		Patients With Events (%)	53 (54.1)	65 (63.7)	
		Patients Without Events (Censored) (%)	45 (45.9)	37 (36.3)	
		Median Time (months) [a]	5.5	2.6	
		95% CI	(2.4, 7.3)	(1.7, 3.4)	
		Log-rank p-value (Unstratified) [b]			0.0210
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.653
		95% CI for Hazard Ratio			(0.452, 0.943)
	No	Number of Patients	71	57	
		Patients With Events (%)	42 (59.2)	25 (43.9)	
		Patients Without Events (Censored) (%)	29 (40.8)	32 (56.1)	
		Median Time (months) [a]	3.7	6.3	
		95% CI	(2.8, 6.1)	(2.8, 12.6)	
		Log-rank p-value (Unstratified) [b]			0.1677
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.413
		95% CI for Hazard Ratio			(0.859, 2.324)
		P-value of Subgroup*Treatment Interaction [d]			0.0161

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Yes	Number of Patients	101	104	
		Patients With Events (%)	45 (44.6)	55 (52.9)	
		Patients Without Events (Censored) (%)	56 (55.4)	49 (47.1)	
		Median Time (months) [a]	6.7	3.1	
		95% CI	(4.6, 9.5)	(2.0, 7.7)	
		Log-rank p-value (Unstratified) [b]			0.0119
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.604
		95% CI for Hazard Ratio			(0.406, 0.900)
	No	Number of Patients	69	57	
		Patients With Events (%)	33 (47.8)	29 (50.9)	
		Patients Without Events (Censored) (%)	36 (52.2)	28 (49.1)	
		Median Time (months) [a]	5.0	4.5	
		95% CI	(2.9, NE)	(2.1, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.4765
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.834
		95% CI for Hazard Ratio			(0.503, 1.381)
		P-value of Subgroup*Treatment Interaction [d]			0.3671
Insomnia	Yes	Number of Patients	97	97	
		Patients With Events (%)	49 (50.5)	46 (47.4)	
		Patients Without Events (Censored) (%)	48 (49.5)	51 (52.6)	
		Median Time (months) [a]	6.3	3.5	
		95% CI	(4.0, 12.5)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.2881
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.803
		95% CI for Hazard Ratio			(0.533, 1.209)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	63	53	
		Patients With Events (%)	19 (30.2)	23 (43.4)	
		Patients Without Events (Censored) (%)	44 (69.8)	30 (56.6)	
		Median Time (months) [a]	18.2	3.9	
		95% CI	(6.0, NE)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.0161
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.481
		95% CI for Hazard Ratio			(0.260, 0.889)
		P-value of Subgroup*Treatment Interaction [d]			0.1330
Appetite Loss	Yes	Number of Patients	98	102	
		Patients With Events (%)	58 (59.2)	54 (52.9)	
		Patients Without Events (Censored) (%)	40 (40.8)	48 (47.1)	
		Median Time (months) [a]	2.9	3.5	
		95% CI	(1.7, 6.0)	(2.1, 5.3)	
		Log-rank p-value (Unstratified) [b]			0.9931
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.998
		95% CI for Hazard Ratio			(0.687, 1.451)
	No	Number of Patients	69	54	
		Patients With Events (%)	39 (56.5)	24 (44.4)	
		Patients Without Events (Censored) (%)	30 (43.5)	30 (55.6)	
		Median Time (months) [a]	4.4	4.9	
		95% CI	(1.7, 9.1)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.4289
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.226
		95% CI for Hazard Ratio			(0.735, 2.046)
		P-value of Subgroup*Treatment Interaction [d]			0.4945

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Yes	Number of Patients	99	104	
		Patients With Events (%)	48 (48.5)	50 (48.1)	
		Patients Without Events (Censored) (%)	51 (51.5)	54 (51.9)	
		Median Time (months) [a]	5.6	4.6	
		95% CI	(3.2, 14.4)	(3.1, 6.7)	
		Log-rank p-value (Unstratified) [b]			0.6416
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.910
		95% CI for Hazard Ratio			(0.611, 1.356)
	No	Number of Patients	71	54	
		Patients With Events (%)	35 (49.3)	20 (37.0)	
		Patients Without Events (Censored) (%)	36 (50.7)	34 (63.0)	
		Median Time (months) [a]	3.8	8.2	
		95% CI	(2.1, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.3645
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.287
		95% CI for Hazard Ratio			(0.743, 2.229)
		P-value of Subgroup*Treatment Interaction [d]			0.3626
Diarrhea	Yes	Number of Patients	101	106	
		Patients With Events (%)	60 (59.4)	40 (37.7)	
		Patients Without Events (Censored) (%)	41 (40.6)	66 (62.3)	
		Median Time (months) [a]	2.1	7.7	
		95% CI	(1.5, 4.4)	(5.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0008
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.952
		95% CI for Hazard Ratio			(1.307, 2.914)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	71	58	
		Patients With Events (%)	44 (62.0)	15 (25.9)	
		Patients Without Events (Censored) (%)	27 (38.0)	43 (74.1)	
		Median Time (months) [a]	2.0	NE	
		95% CI	(1.4, 3.4)	(5.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			3.076
		95% CI for Hazard Ratio			(1.704, 5.553)
		P-value of Subgroup*Treatment Interaction [d]			0.1799
Financial Difficulties	Yes	Number of Patients	100	102	
		Patients With Events (%)	28 (28.0)	22 (21.6)	
		Patients Without Events (Censored) (%)	72 (72.0)	80 (78.4)	
		Median Time (months) [a]	NE	NE	
		95% CI	(7.2, NE)	(8.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.6483
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.139
		95% CI for Hazard Ratio			(0.650, 1.995)
	No	Number of Patients	69	57	
		Patients With Events (%)	15 (21.7)	9 (15.8)	
		Patients Without Events (Censored) (%)	54 (78.3)	48 (84.2)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.7176
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.165
		95% CI for Hazard Ratio			(0.508, 2.669)
		P-value of Subgroup*Treatment Interaction [d]			0.9712

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.10
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Chemotherapy in neo/adjuvant setting
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Yes	Number of Patients	103	107	
		Patients With Events (%)	48 (46.6)	58 (54.2)	
		Patients Without Events (Censored) (%)	55 (53.4)	49 (45.8)	
		Median Time (months) [a]	6.6	3.7	
		95% CI	(4.3, 23.6)	(2.8, 5.3)	
		Log-rank p-value (Unstratified) [b]			0.0310
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.655
		95% CI for Hazard Ratio			(0.444, 0.966)
	No	Number of Patients	71	58	
		Patients With Events (%)	37 (52.1)	21 (36.2)	
		Patients Without Events (Censored) (%)	34 (47.9)	37 (63.8)	
		Median Time (months) [a]	3.9	9.9	
		95% CI	(2.9, 9.2)	(8.2, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.1950
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.423
		95% CI for Hazard Ratio			(0.830, 2.438)
		P-value of Subgroup*Treatment Interaction [d]			0.0223

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	<100	Number of Patients	59	61	
		Patients With Events (%)	33 (55.9)	41 (67.2)	
		Patients Without Events (Censored) (%)	26 (44.1)	20 (32.8)	
		Median Time (months) [a]	4.3	2.7	
		95% CI	(1.7, 8.0)	(1.8, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.1930
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.739
		95% CI for Hazard Ratio			(0.466, 1.171)
	≥100 to ≤200	Number of Patients	58	58	
		Patients With Events (%)	31 (53.4)	31 (53.4)	
		Patients Without Events (Censored) (%)	27 (46.6)	27 (46.6)	
		Median Time (months) [a]	4.9	3.0	
		95% CI	(2.6, 8.1)	(2.2, 5.1)	
		Log-rank p-value (Unstratified) [b]			0.2348
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.739
		95% CI for Hazard Ratio			(0.446, 1.224)
	>200	Number of Patients	34	25	
		Patients With Events (%)	20 (58.8)	18 (72.0)	
		Patients Without Events (Censored) (%)	14 (41.2)	7 (28.0)	
		Median Time (months) [a]	6.7	1.7	
		95% CI	(2.0, 10.6)	(1.0, 4.2)	
		Log-rank p-value (Unstratified) [b]			0.0597
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.543
		95% CI for Hazard Ratio			(0.284, 1.038)
		P-value of Subgroup*Treatment Interaction [d]			0.6792

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Physical Functioning	<100	Number of Patients	60	61	
		Patients With Events (%)	33 (55.0)	33 (54.1)	
		Patients Without Events (Censored) (%)	27 (45.0)	28 (45.9)	
		Median Time (months) [a]	3.1	4.6	
		95% CI	(2.1, 10.3)	(2.2, 7.3)	
		Log-rank p-value (Unstratified) [b]			0.8138
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.944
		95% CI for Hazard Ratio			(0.582, 1.530)
	≥100 to ≤200	Number of Patients	58	58	
		Patients With Events (%)	25 (43.1)	31 (53.4)	
		Patients Without Events (Censored) (%)	33 (56.9)	27 (46.6)	
		Median Time (months) [a]	6.7	2.7	
		95% CI	(3.0, NE)	(1.9, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.0133
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.509
		95% CI for Hazard Ratio			(0.294, 0.879)
	>200	Number of Patients	34	25	
		Patients With Events (%)	21 (61.8)	14 (56.0)	
		Patients Without Events (Censored) (%)	13 (38.2)	11 (44.0)	
		Median Time (months) [a]	4.0	3.4	
		95% CI	(1.7, 13.1)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.7311
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.888
		95% CI for Hazard Ratio			(0.450, 1.753)
		P-value of Subgroup*Treatment Interaction [d]			0.2255

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Role Functioning	<100	Number of Patients	58	60	
		Patients With Events (%)	36 (62.1)	39 (65.0)	
		Patients Without Events (Censored) (%)	22 (37.9)	21 (35.0)	
		Median Time (months) [a]	2.8	2.1	
		95% CI	(1.7, 5.0)	(1.3, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.3803
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.818
		95% CI for Hazard Ratio			(0.519, 1.288)
	≥100 to ≤200	Number of Patients	58	55	
		Patients With Events (%)	37 (63.8)	33 (60.0)	
		Patients Without Events (Censored) (%)	21 (36.2)	22 (40.0)	
		Median Time (months) [a]	4.2	2.2	
		95% CI	(1.8, 6.1)	(1.4, 3.0)	
		Log-rank p-value (Unstratified) [b]			0.0551
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.623
		95% CI for Hazard Ratio			(0.381, 1.020)
	>200	Number of Patients	34	24	
		Patients With Events (%)	26 (76.5)	17 (70.8)	
		Patients Without Events (Censored) (%)	8 (23.5)	7 (29.2)	
		Median Time (months) [a]	1.5	2.2	
		95% CI	(1.1, 2.9)	(1.0, 3.4)	
		Log-rank p-value (Unstratified) [b]			0.8193
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.073
		95% CI for Hazard Ratio			(0.581, 1.982)
		P-value of Subgroup*Treatment Interaction [d]			0.5602

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	<100	Number of Patients	59	60	
		Patients With Events (%)	20 (33.9)	27 (45.0)	
		Patients Without Events (Censored) (%)	39 (66.1)	33 (55.0)	
		Median Time (months) [a]	8.9	4.5	
		95% CI	(4.7, NE)	(3.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.1237
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.637
		95% CI for Hazard Ratio			(0.357, 1.138)
	≥100 to ≤200	Number of Patients	56	59	
		Patients With Events (%)	21 (37.5)	28 (47.5)	
		Patients Without Events (Censored) (%)	35 (62.5)	31 (52.5)	
		Median Time (months) [a]	7.2	3.9	
		95% CI	(4.5, NE)	(1.8, 7.2)	
		Log-rank p-value (Unstratified) [b]			0.0431
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.561
		95% CI for Hazard Ratio			(0.317, 0.994)
	>200	Number of Patients	32	25	
		Patients With Events (%)	13 (40.6)	10 (40.0)	
		Patients Without Events (Censored) (%)	19 (59.4)	15 (60.0)	
		Median Time (months) [a]	12.8	NE	
		95% CI	(2.9, NE)	(3.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.8337
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.092
		95% CI for Hazard Ratio			(0.478, 2.493)
		P-value of Subgroup*Treatment Interaction [d]			0.3885

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Cognitive Functioning	<100	Number of Patients	60	61	
		Patients With Events (%)	33 (55.0)	25 (41.0)	
		Patients Without Events (Censored) (%)	27 (45.0)	36 (59.0)	
		Median Time (months) [a]	2.6	8.2	
		95% CI	(1.7, 6.6)	(3.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.1616
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.446
		95% CI for Hazard Ratio			(0.858, 2.435)
	≥100 to ≤200	Number of Patients	58	58	
		Patients With Events (%)	29 (50.0)	22 (37.9)	
		Patients Without Events (Censored) (%)	29 (50.0)	36 (62.1)	
		Median Time (months) [a]	5.6	4.3	
		95% CI	(2.3, 11.1)	(2.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.7664
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.917
		95% CI for Hazard Ratio			(0.517, 1.627)
	>200	Number of Patients	34	25	
		Patients With Events (%)	16 (47.1)	12 (48.0)	
		Patients Without Events (Censored) (%)	18 (52.9)	13 (52.0)	
		Median Time (months) [a]	15.2	4.3	
		95% CI	(2.8, NE)	(1.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.5650
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.800
		95% CI for Hazard Ratio			(0.373, 1.714)
		P-value of Subgroup*Treatment Interaction [d]			0.4008

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Social Functioning	<100	Number of Patients	58	60	
		Patients With Events (%)	35 (60.3)	35 (58.3)	
		Patients Without Events (Censored) (%)	23 (39.7)	25 (41.7)	
		Median Time (months) [a]	2.3	2.9	
		95% CI	(1.7, 6.0)	(1.8, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.7988
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.941
		95% CI for Hazard Ratio			(0.586, 1.510)
	≥100 to ≤200	Number of Patients	56	55	
		Patients With Events (%)	30 (53.6)	29 (52.7)	
		Patients Without Events (Censored) (%)	26 (46.4)	26 (47.3)	
		Median Time (months) [a]	3.1	3.7	
		95% CI	(1.7, NE)	(2.1, 4.4)	
		Log-rank p-value (Unstratified) [b]			0.5769
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.864
		95% CI for Hazard Ratio			(0.515, 1.450)
	>200	Number of Patients	34	23	
		Patients With Events (%)	23 (67.6)	15 (65.2)	
		Patients Without Events (Censored) (%)	11 (32.4)	8 (34.8)	
		Median Time (months) [a]	1.7	3.6	
		95% CI	(1.1, 4.6)	(1.4, 5.8)	
		Log-rank p-value (Unstratified) [b]			0.7831
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.095
		95% CI for Hazard Ratio			(0.570, 2.103)
		P-value of Subgroup*Treatment Interaction [d]			0.9010

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	<100	Number of Patients	59	61	
		Patients With Events (%)	41 (69.5)	48 (78.7)	
		Patients Without Events (Censored) (%)	18 (30.5)	13 (21.3)	
		Median Time (months) [a]	1.9	1.1	
		95% CI	(1.3, 4.2)	(0.9, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0804
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.692
		95% CI for Hazard Ratio			(0.455, 1.055)
	≥100 to ≤200	Number of Patients	57	56	
		Patients With Events (%)	37 (64.9)	38 (67.9)	
		Patients Without Events (Censored) (%)	20 (35.1)	18 (32.1)	
		Median Time (months) [a]	2.3	1.1	
		95% CI	(1.3, 4.5)	(0.9, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.0642
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.651
		95% CI for Hazard Ratio			(0.408, 1.037)
	>200	Number of Patients	34	25	
		Patients With Events (%)	27 (79.4)	22 (88.0)	
		Patients Without Events (Censored) (%)	7 (20.6)	3 (12.0)	
		Median Time (months) [a]	1.7	1.5	
		95% CI	(1.0, 3.1)	(0.9, 2.8)	
		Log-rank p-value (Unstratified) [b]			0.3991
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.788
		95% CI for Hazard Ratio			(0.447, 1.387)
		P-value of Subgroup*Treatment Interaction [d]			0.8583

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Nausea and Vomiting	<100	Number of Patients	60	61	
		Patients With Events (%)	36 (60.0)	27 (44.3)	
		Patients Without Events (Censored) (%)	24 (40.0)	34 (55.7)	
		Median Time (months) [a]	2.6	7.4	
		95% CI	(1.5, 5.6)	(2.8, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.1045
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.502
		95% CI for Hazard Ratio			(0.911, 2.478)
	≥100 to ≤200	Number of Patients	58	59	
		Patients With Events (%)	39 (67.2)	24 (40.7)	
		Patients Without Events (Censored) (%)	19 (32.8)	35 (59.3)	
		Median Time (months) [a]	1.5	7.2	
		95% CI	(1.3, 4.7)	(1.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.1247
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.485
		95% CI for Hazard Ratio			(0.887, 2.486)
	>200	Number of Patients	34	25	
		Patients With Events (%)	21 (61.8)	18 (72.0)	
		Patients Without Events (Censored) (%)	13 (38.2)	7 (28.0)	
		Median Time (months) [a]	2.1	2.2	
		95% CI	(1.4, 14.4)	(1.0, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.4412
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.781
		95% CI for Hazard Ratio			(0.412, 1.479)
		P-value of Subgroup*Treatment Interaction [d]			0.2086

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Pain	<100	Number of Patients	59	61	
		Patients With Events (%)	25 (42.4)	33 (54.1)	
		Patients Without Events (Censored) (%)	34 (57.6)	28 (45.9)	
		Median Time (months) [a]	6.7	3.3	
		95% CI	(3.7, NE)	(2.2, 6.3)	
		Log-rank p-value (Unstratified) [b]			0.0728
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.622
		95% CI for Hazard Ratio			(0.367, 1.053)
	≥100 to ≤200	Number of Patients	56	54	
		Patients With Events (%)	33 (58.9)	29 (53.7)	
		Patients Without Events (Censored) (%)	23 (41.1)	25 (46.3)	
		Median Time (months) [a]	3.7	2.6	
		95% CI	(1.8, 5.9)	(1.4, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.4538
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.826
		95% CI for Hazard Ratio			(0.498, 1.370)
	>200	Number of Patients	33	24	
		Patients With Events (%)	24 (72.7)	15 (62.5)	
		Patients Without Events (Censored) (%)	9 (27.3)	9 (37.5)	
		Median Time (months) [a]	3.6	5.7	
		95% CI	(1.4, 6.5)	(1.4, 10.3)	
		Log-rank p-value (Unstratified) [b]			0.4938
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.251
		95% CI for Hazard Ratio			(0.656, 2.389)
		P-value of Subgroup*Treatment Interaction [d]			0.2238

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	<100	Number of Patients	58	60	
		Patients With Events (%)	26 (44.8)	33 (55.0)	
		Patients Without Events (Censored) (%)	32 (55.2)	27 (45.0)	
		Median Time (months) [a]	6.6	5.6	
		95% CI	(4.3, 9.5)	(1.7, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.1019
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.654
		95% CI for Hazard Ratio			(0.390, 1.096)
	≥100 to ≤200	Number of Patients	57	57	
		Patients With Events (%)	25 (43.9)	31 (54.4)	
		Patients Without Events (Censored) (%)	32 (56.1)	26 (45.6)	
		Median Time (months) [a]	5.9	3.0	
		95% CI	(3.1, NE)	(1.5, 3.9)	
		Log-rank p-value (Unstratified) [b]			0.0361
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.571
		95% CI for Hazard Ratio			(0.335, 0.973)
	>200	Number of Patients	34	25	
		Patients With Events (%)	16 (47.1)	12 (48.0)	
		Patients Without Events (Censored) (%)	18 (52.9)	13 (52.0)	
		Median Time (months) [a]	14.4	4.5	
		95% CI	(1.2, 18.2)	(1.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.7774
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.896
		95% CI for Hazard Ratio			(0.417, 1.925)
		P-value of Subgroup*Treatment Interaction [d]			0.5841

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Insomnia	<100	Number of Patients	55	59	
		Patients With Events (%)	25 (45.5)	26 (44.1)	
		Patients Without Events (Censored) (%)	30 (54.5)	33 (55.9)	
		Median Time (months) [a]	6.6	7.4	
		95% CI	(3.0, NE)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.3767
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.781
		95% CI for Hazard Ratio			(0.449, 1.357)
	≥100 to ≤200	Number of Patients	54	49	
		Patients With Events (%)	19 (35.2)	22 (44.9)	
		Patients Without Events (Censored) (%)	35 (64.8)	27 (55.1)	
		Median Time (months) [a]	18.9	3.1	
		95% CI	(6.0, NE)	(1.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.0115
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.446
		95% CI for Hazard Ratio			(0.234, 0.852)
	>200	Number of Patients	30	22	
		Patients With Events (%)	13 (43.3)	13 (59.1)	
		Patients Without Events (Censored) (%)	17 (56.7)	9 (40.9)	
		Median Time (months) [a]	18.2	3.9	
		95% CI	(2.1, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.2530
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.639
		95% CI for Hazard Ratio			(0.291, 1.401)
		P-value of Subgroup*Treatment Interaction [d]			0.4478

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Appetite Loss	<100	Number of Patients	57	56	
		Patients With Events (%)	32 (56.1)	32 (57.1)	
		Patients Without Events (Censored) (%)	25 (43.9)	24 (42.9)	
		Median Time (months) [a]	3.3	2.8	
		95% CI	(1.7, 5.5)	(1.5, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.8990
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.969
		95% CI for Hazard Ratio			(0.593, 1.582)
	≥100 to ≤200	Number of Patients	56	57	
		Patients With Events (%)	36 (64.3)	28 (49.1)	
		Patients Without Events (Censored) (%)	20 (35.7)	29 (50.9)	
		Median Time (months) [a]	2.8	3.1	
		95% CI	(1.5, 6.0)	(1.5, 8.2)	
		Log-rank p-value (Unstratified) [b]			0.8828
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.038
		95% CI for Hazard Ratio			(0.627, 1.718)
	>200	Number of Patients	33	24	
		Patients With Events (%)	21 (63.6)	10 (41.7)	
		Patients Without Events (Censored) (%)	12 (36.4)	14 (58.3)	
		Median Time (months) [a]	4.4	9.6	
		95% CI	(1.7, 10.6)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.3319
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.453
		95% CI for Hazard Ratio			(0.679, 3.111)
		P-value of Subgroup*Treatment Interaction [d]			0.6295

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	<100	Number of Patients	58	58	
		Patients With Events (%)	31 (53.4)	22 (37.9)	
		Patients Without Events (Censored) (%)	27 (46.6)	36 (62.1)	
		Median Time (months) [a]	3.7	5.7	
		95% CI	(1.6, 13.9)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.0998
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.577
		95% CI for Hazard Ratio			(0.911, 2.730)
	≥100 to ≤200	Number of Patients	57	56	
		Patients With Events (%)	21 (36.8)	32 (57.1)	
		Patients Without Events (Censored) (%)	36 (63.2)	24 (42.9)	
		Median Time (months) [a]	8.4	2.3	
		95% CI	(4.2, NE)	(1.4, 3.8)	
		Log-rank p-value (Unstratified) [b]			0.0011
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.402
		95% CI for Hazard Ratio			(0.228, 0.709)
	>200	Number of Patients	33	24	
		Patients With Events (%)	17 (51.5)	8 (33.3)	
		Patients Without Events (Censored) (%)	16 (48.5)	16 (66.7)	
		Median Time (months) [a]	7.8	NE	
		95% CI	(1.6, NE)	(2.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.2133
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.694
		95% CI for Hazard Ratio			(0.730, 3.929)
		P-value of Subgroup*Treatment Interaction [d]			0.0006

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Diarrhea	<100	Number of Patients	60	61	
		Patients With Events (%)	33 (55.0)	16 (26.2)	
		Patients Without Events (Censored) (%)	27 (45.0)	45 (73.8)	
		Median Time (months) [a]	2.4	10.9	
		95% CI	(1.5, 16.5)	(7.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.0007
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.699
		95% CI for Hazard Ratio			(1.481, 4.920)
	≥100 to ≤200	Number of Patients	57	59	
		Patients With Events (%)	40 (70.2)	18 (30.5)	
		Patients Without Events (Censored) (%)	17 (29.8)	41 (69.5)	
		Median Time (months) [a]	1.5	5.8	
		95% CI	(1.0, 2.3)	(3.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.930
		95% CI for Hazard Ratio			(1.671, 5.136)
	>200	Number of Patients	34	24	
		Patients With Events (%)	19 (55.9)	12 (50.0)	
		Patients Without Events (Censored) (%)	15 (44.1)	12 (50.0)	
		Median Time (months) [a]	4.4	5.9	
		95% CI	(2.0, 7.9)	(2.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.3688
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.396
		95% CI for Hazard Ratio			(0.671, 2.905)
		P-value of Subgroup*Treatment Interaction [d]			0.1862

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Financial Difficulties	<100	Number of Patients	56	59	
		Patients With Events (%)	12 (21.4)	10 (16.9)	
		Patients Without Events (Censored) (%)	44 (78.6)	49 (83.1)	
		Median Time (months) [a]	NE	NE	
		95% CI	(7.2, NE)	(8.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.6972
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.181
		95% CI for Hazard Ratio			(0.510, 2.736)
	≥100 to ≤200	Number of Patients	57	58	
		Patients With Events (%)	13 (22.8)	15 (25.9)	
		Patients Without Events (Censored) (%)	44 (77.2)	43 (74.1)	
		Median Time (months) [a]	NE	NE	
		95% CI	(NE, NE)	(3.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.2643
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.656
		95% CI for Hazard Ratio			(0.310, 1.387)
	>200	Number of Patients	34	23	
		Patients With Events (%)	12 (35.3)	5 (21.7)	
		Patients Without Events (Censored) (%)	22 (64.7)	18 (78.3)	
		Median Time (months) [a]	18.2	NE	
		95% CI	(4.6, NE)	(4.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.5110
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.423
		95% CI for Hazard Ratio			(0.494, 4.101)
		P-value of Subgroup*Treatment Interaction [d]			0.3049

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.11
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Trop2 H-Score
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	<100	Number of Patients	60	61	
		Patients With Events (%)	29 (48.3)	28 (45.9)	
		Patients Without Events (Censored) (%)	31 (51.7)	33 (54.1)	
		Median Time (months) [a]	4.9	6.4	
		95% CI	(1.7, NE)	(2.7, 12.7)	
		Log-rank p-value (Unstratified) [b]			0.7952
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.071
		95% CI for Hazard Ratio			(0.637, 1.801)
	≥100 to ≤200	Number of Patients	58	59	
		Patients With Events (%)	29 (50.0)	28 (47.5)	
		Patients Without Events (Censored) (%)	29 (50.0)	31 (52.5)	
		Median Time (months) [a]	5.6	3.7	
		95% CI	(3.0, 9.2)	(2.2, 7.2)	
		Log-rank p-value (Unstratified) [b]			0.1939
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.706
		95% CI for Hazard Ratio			(0.415, 1.200)
	>200	Number of Patients	34	25	
		Patients With Events (%)	17 (50.0)	13 (52.0)	
		Patients Without Events (Censored) (%)	17 (50.0)	12 (48.0)	
		Median Time (months) [a]	9.3	9.5	
		95% CI	(2.9, NE)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.7254
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.878
		95% CI for Hazard Ratio			(0.425, 1.816)
		P-value of Subgroup*Treatment Interaction [d]			0.6005

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	10 (50.0)	13 (65.0)	
		Patients Without Events (Censored) (%)	10 (50.0)	7 (35.0)	
		Median Time (months) [a]	5.6	1.9	
		95% CI	(1.3, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.2269
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.605
		95% CI for Hazard Ratio			(0.265, 1.384)
	Eribulin	Number of Patients	107	106	
		Patients With Events (%)	65 (60.7)	68 (64.2)	
		Patients Without Events (Censored) (%)	42 (39.3)	38 (35.8)	
		Median Time (months) [a]	3.7	3.0	
		95% CI	(1.9, 6.1)	(2.2, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.4853
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.886
		95% CI for Hazard Ratio			(0.630, 1.246)
	Vinorelbine	Number of Patients	46	38	
		Patients With Events (%)	20 (43.5)	22 (57.9)	
		Patients Without Events (Censored) (%)	26 (56.5)	16 (42.1)	
		Median Time (months) [a]	8.1	1.8	
		95% CI	(4.4, NE)	(1.1, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.0003
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.305
		95% CI for Hazard Ratio			(0.156, 0.597)
		P-value of Subgroup*Treatment Interaction [d]			0.0213

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Physical Functioning	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	9 (45.0)	11 (55.0)	
		Patients Without Events (Censored) (%)	11 (55.0)	9 (45.0)	
		Median Time (months) [a]	6.1	3.5	
		95% CI	(1.4, NE)	(1.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.6625
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.822
		95% CI for Hazard Ratio			(0.340, 1.987)
	Eribulin	Number of Patients	107	107	
		Patients With Events (%)	59 (55.1)	63 (58.9)	
		Patients Without Events (Censored) (%)	48 (44.9)	44 (41.1)	
		Median Time (months) [a]	4.0	2.7	
		95% CI	(2.1, 9.1)	(2.2, 4.6)	
		Log-rank p-value (Unstratified) [b]			0.2160
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.799
		95% CI for Hazard Ratio			(0.559, 1.143)
	Vinorelbine	Number of Patients	47	37	
		Patients With Events (%)	20 (42.6)	13 (35.1)	
		Patients Without Events (Censored) (%)	27 (57.4)	24 (64.9)	
		Median Time (months) [a]	7.1	3.7	
		95% CI	(4.2, NE)	(1.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.1900
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.623
		95% CI for Hazard Ratio			(0.304, 1.274)
		P-value of Subgroup*Treatment Interaction [d]			0.8893

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Role Functioning	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	12 (60.0)	13 (65.0)	
		Patients Without Events (Censored) (%)	8 (40.0)	7 (35.0)	
		Median Time (months) [a]	2.9	1.9	
		95% CI	(1.3, NE)	(1.0, 5.3)	
		Log-rank p-value (Unstratified) [b]			0.5328
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.781
		95% CI for Hazard Ratio			(0.354, 1.720)
	Eribulin	Number of Patients	106	103	
		Patients With Events (%)	70 (66.0)	65 (63.1)	
		Patients Without Events (Censored) (%)	36 (34.0)	38 (36.9)	
		Median Time (months) [a]	1.9	2.8	
		95% CI	(1.6, 4.3)	(1.4, 3.6)	
		Log-rank p-value (Unstratified) [b]			0.7224
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.941
		95% CI for Hazard Ratio			(0.670, 1.322)
	Vinorelbine	Number of Patients	45	36	
		Patients With Events (%)	29 (64.4)	24 (66.7)	
		Patients Without Events (Censored) (%)	16 (35.6)	12 (33.3)	
		Median Time (months) [a]	3.7	1.8	
		95% CI	(1.9, 6.7)	(1.0, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.0017
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.401
		95% CI for Hazard Ratio			(0.222, 0.726)
		P-value of Subgroup*Treatment Interaction [d]			0.1242

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Capecitabine	Number of Patients	18	20	
		Patients With Events (%)	4 (22.2)	9 (45.0)	
		Patients Without Events (Censored) (%)	14 (77.8)	11 (55.0)	
		Median Time (months) [a]	NE	9.5	
		95% CI	(2.9, NE)	(1.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.1694
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.446
		95% CI for Hazard Ratio			(0.137, 1.455)
	Eribulin	Number of Patients	104	106	
		Patients With Events (%)	41 (39.4)	49 (46.2)	
		Patients Without Events (Censored) (%)	63 (60.6)	57 (53.8)	
		Median Time (months) [a]	8.9	4.7	
		95% CI	(4.7, NE)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.2757
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.795
		95% CI for Hazard Ratio			(0.525, 1.205)
	Vinorelbine	Number of Patients	47	38	
		Patients With Events (%)	16 (34.0)	17 (44.7)	
		Patients Without Events (Censored) (%)	31 (66.0)	21 (55.3)	
		Median Time (months) [a]	NE	3.1	
		95% CI	(4.2, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.0039
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.359
		95% CI for Hazard Ratio			(0.174, 0.740)
		P-value of Subgroup*Treatment Interaction [d]			0.1247

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Cognitive Functioning	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	8 (40.0)	11 (55.0)	
		Patients Without Events (Censored) (%)	12 (60.0)	9 (45.0)	
		Median Time (months) [a]	18.2	3.0	
		95% CI	(1.3, 18.2)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.2669
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.589
		95% CI for Hazard Ratio			(0.228, 1.522)
	Eribulin	Number of Patients	107	106	
		Patients With Events (%)	60 (56.1)	44 (41.5)	
		Patients Without Events (Censored) (%)	47 (43.9)	62 (58.5)	
		Median Time (months) [a]	3.7	7.2	
		95% CI	(2.5, 6.6)	(4.3, NE)	
		Log-rank p-value (Unstratified) [b]			0.1708
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.311
		95% CI for Hazard Ratio			(0.887, 1.939)
	Vinorelbine	Number of Patients	47	38	
		Patients With Events (%)	18 (38.3)	12 (31.6)	
		Patients Without Events (Censored) (%)	29 (61.7)	26 (68.4)	
		Median Time (months) [a]	11.1	4.4	
		95% CI	(2.8, NE)	(2.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.4465
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.747
		95% CI for Hazard Ratio			(0.350, 1.593)
		P-value of Subgroup*Treatment Interaction [d]			0.1958

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Social Functioning	Capecitabine	Number of Patients	19	20	
		Patients With Events (%)	8 (42.1)	10 (50.0)	
		Patients Without Events (Censored) (%)	11 (57.9)	10 (50.0)	
		Median Time (months) [a]	NE	5.4	
		95% CI	(1.0, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.8405
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.909
		95% CI for Hazard Ratio			(0.358, 2.314)
	Eribulin	Number of Patients	104	102	
		Patients With Events (%)	67 (64.4)	61 (59.8)	
		Patients Without Events (Censored) (%)	37 (35.6)	41 (40.2)	
		Median Time (months) [a]	2.1	3.1	
		95% CI	(1.7, 3.6)	(2.4, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.6041
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.096
		95% CI for Hazard Ratio			(0.773, 1.553)
	Vinorelbine	Number of Patients	47	35	
		Patients With Events (%)	26 (55.3)	17 (48.6)	
		Patients Without Events (Censored) (%)	21 (44.7)	18 (51.4)	
		Median Time (months) [a]	3.5	2.9	
		95% CI	(1.2, NE)	(1.1, 6.7)	
		Log-rank p-value (Unstratified) [b]			0.5810
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.840
		95% CI for Hazard Ratio			(0.448, 1.574)
		P-value of Subgroup*Treatment Interaction [d]			0.6477

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	15 (75.0)	16 (80.0)	
		Patients Without Events (Censored) (%)	5 (25.0)	4 (20.0)	
		Median Time (months) [a]	1.3	0.8	
		95% CI	(0.9, 2.4)	(0.8, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.1650
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.617
		95% CI for Hazard Ratio			(0.303, 1.254)
	Eribulin	Number of Patients	106	106	
		Patients With Events (%)	77 (72.6)	79 (74.5)	
		Patients Without Events (Censored) (%)	29 (27.4)	27 (25.5)	
		Median Time (months) [a]	1.7	1.4	
		95% CI	(1.4, 2.9)	(1.0, 2.3)	
		Log-rank p-value (Unstratified) [b]			0.3618
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.865
		95% CI for Hazard Ratio			(0.631, 1.186)
	Vinorelbine	Number of Patients	46	36	
		Patients With Events (%)	29 (63.0)	29 (80.6)	
		Patients Without Events (Censored) (%)	17 (37.0)	7 (19.4)	
		Median Time (months) [a]	2.6	1.1	
		95% CI	(1.7, 6.7)	(0.9, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.332
		95% CI for Hazard Ratio			(0.187, 0.588)
		P-value of Subgroup*Treatment Interaction [d]			0.0165

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Nausea and Vomiting	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	11 (55.0)	12 (60.0)	
		Patients Without Events (Censored) (%)	9 (45.0)	8 (40.0)	
		Median Time (months) [a]	2.4	4.6	
		95% CI	(0.8, NE)	(0.8, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.9090
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.954
		95% CI for Hazard Ratio			(0.416, 2.188)
	Eribulin	Number of Patients	106	107	
		Patients With Events (%)	68 (64.2)	50 (46.7)	
		Patients Without Events (Censored) (%)	38 (35.8)	57 (53.3)	
		Median Time (months) [a]	2.1	7.2	
		95% CI	(1.5, 4.2)	(2.9, 10.3)	
		Log-rank p-value (Unstratified) [b]			0.0712
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.396
		95% CI for Hazard Ratio			(0.967, 2.017)
	Vinorelbine	Number of Patients	47	38	
		Patients With Events (%)	27 (57.4)	15 (39.5)	
		Patients Without Events (Censored) (%)	20 (42.6)	23 (60.5)	
		Median Time (months) [a]	2.6	3.7	
		95% CI	(1.2, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.5400
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.219
		95% CI for Hazard Ratio			(0.640, 2.324)
		P-value of Subgroup*Treatment Interaction [d]			0.5717

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Pain	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	10 (50.0)	11 (55.0)	
		Patients Without Events (Censored) (%)	10 (50.0)	9 (45.0)	
		Median Time (months) [a]	5.0	3.5	
		95% CI	(1.7, NE)	(1.4, 12.6)	
		Log-rank p-value (Unstratified) [b]			0.8610
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.084
		95% CI for Hazard Ratio			(0.439, 2.675)
	Eribulin	Number of Patients	104	104	
		Patients With Events (%)	62 (59.6)	62 (59.6)	
		Patients Without Events (Censored) (%)	42 (40.4)	42 (40.4)	
		Median Time (months) [a]	3.7	3.3	
		95% CI	(1.8, 6.1)	(2.2, 5.7)	
		Log-rank p-value (Unstratified) [b]			0.6372
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.919
		95% CI for Hazard Ratio			(0.646, 1.309)
	Vinorelbine	Number of Patients	45	35	
		Patients With Events (%)	23 (51.1)	17 (48.6)	
		Patients Without Events (Censored) (%)	22 (48.9)	18 (51.4)	
		Median Time (months) [a]	5.9	2.1	
		95% CI	(2.4, NE)	(1.3, 3.4)	
		Log-rank p-value (Unstratified) [b]			0.0927
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.566
		95% CI for Hazard Ratio			(0.286, 1.120)
		P-value of Subgroup*Treatment Interaction [d]			0.4690

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Capecitabine	Number of Patients	19	20	
		Patients With Events (%)	10 (52.6)	7 (35.0)	
		Patients Without Events (Censored) (%)	9 (47.4)	13 (65.0)	
		Median Time (months) [a]	3.1	8.4	
		95% CI	(1.4, 18.2)	(1.9, 8.4)	
		Log-rank p-value (Unstratified) [b]			0.5990
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.301
		95% CI for Hazard Ratio			(0.483, 3.506)
	Eribulin	Number of Patients	106	106	
		Patients With Events (%)	47 (44.3)	59 (55.7)	
		Patients Without Events (Censored) (%)	59 (55.7)	47 (44.3)	
		Median Time (months) [a]	6.7	3.9	
		95% CI	(4.5, 14.4)	(2.2, 7.7)	
		Log-rank p-value (Unstratified) [b]			0.0229
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.643
		95% CI for Hazard Ratio			(0.437, 0.945)
	Vinorelbine	Number of Patients	45	35	
		Patients With Events (%)	21 (46.7)	18 (51.4)	
		Patients Without Events (Censored) (%)	24 (53.3)	17 (48.6)	
		Median Time (months) [a]	5.9	2.0	
		95% CI	(3.3, NE)	(1.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.0781
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.562
		95% CI for Hazard Ratio			(0.292, 1.081)
		P-value of Subgroup*Treatment Interaction [d]			0.2171

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Insomnia	Capecitabine	Number of Patients	19	19	
		Patients With Events (%)	4 (21.1)	15 (78.9)	
		Patients Without Events (Censored) (%)	15 (78.9)	4 (21.1)	
		Median Time (months) [a]	18.2	1.7	
		95% CI	(NE, NE)	(0.8, 3.9)	
		Log-rank p-value (Unstratified) [b]			0.0002
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.136
		95% CI for Hazard Ratio			(0.039, 0.471)
	Eribulin	Number of Patients	96	96	
		Patients With Events (%)	40 (41.7)	46 (47.9)	
		Patients Without Events (Censored) (%)	56 (58.3)	50 (52.1)	
		Median Time (months) [a]	8.7	3.9	
		95% CI	(4.7, NE)	(2.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.1357
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.727
		95% CI for Hazard Ratio			(0.475, 1.112)
	Vinorelbine	Number of Patients	45	35	
		Patients With Events (%)	24 (53.3)	8 (22.9)	
		Patients Without Events (Censored) (%)	21 (46.7)	27 (77.1)	
		Median Time (months) [a]	6.3	NE	
		95% CI	(2.8, 23.6)	(2.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.6867
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.188
		95% CI for Hazard Ratio			(0.510, 2.767)
		P-value of Subgroup*Treatment Interaction [d]			0.0088

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Appetite Loss	Capecitabine	Number of Patients	20	19	
		Patients With Events (%)	8 (40.0)	10 (52.6)	
		Patients Without Events (Censored) (%)	12 (60.0)	9 (47.4)	
		Median Time (months) [a]	NE	4.9	
		95% CI	(1.4, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.8400
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.908
		95% CI for Hazard Ratio			(0.354, 2.328)
	Eribulin	Number of Patients	102	102	
		Patients With Events (%)	63 (61.8)	50 (49.0)	
		Patients Without Events (Censored) (%)	39 (38.2)	52 (51.0)	
		Median Time (months) [a]	3.7	5.3	
		95% CI	(1.7, 5.9)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.2959
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.218
		95% CI for Hazard Ratio			(0.838, 1.769)
	Vinorelbine	Number of Patients	45	35	
		Patients With Events (%)	26 (57.8)	18 (51.4)	
		Patients Without Events (Censored) (%)	19 (42.2)	17 (48.6)	
		Median Time (months) [a]	2.8	2.3	
		95% CI	(1.2, 18.2)	(1.1, 4.4)	
		Log-rank p-value (Unstratified) [b]			0.5377
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.821
		95% CI for Hazard Ratio			(0.436, 1.546)
		P-value of Subgroup*Treatment Interaction [d]			0.3955

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Capecitabine	Number of Patients	19	20	
		Patients With Events (%)	8 (42.1)	9 (45.0)	
		Patients Without Events (Censored) (%)	11 (57.9)	11 (55.0)	
		Median Time (months) [a]	8.6	3.2	
		95% CI	(1.6, NE)	(1.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.8972
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.939
		95% CI for Hazard Ratio			(0.360, 2.448)
	Eribulin	Number of Patients	104	105	
		Patients With Events (%)	53 (51.0)	47 (44.8)	
		Patients Without Events (Censored) (%)	51 (49.0)	58 (55.2)	
		Median Time (months) [a]	5.0	4.9	
		95% CI	(2.5, 13.9)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.6500
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.095
		95% CI for Hazard Ratio			(0.739, 1.622)
	Vinorelbine	Number of Patients	47	33	
		Patients With Events (%)	22 (46.8)	14 (42.4)	
		Patients Without Events (Censored) (%)	25 (53.2)	19 (57.6)	
		Median Time (months) [a]	5.4	4.2	
		95% CI	(1.9, NE)	(1.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.6899
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.870
		95% CI for Hazard Ratio			(0.437, 1.732)
		P-value of Subgroup*Treatment Interaction [d]			0.7510

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Diarrhea	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	13 (65.0)	8 (40.0)	
		Patients Without Events (Censored) (%)	7 (35.0)	12 (60.0)	
		Median Time (months) [a]	1.2	7.7	
		95% CI	(0.8, NE)	(3.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.0339
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.608
		95% CI for Hazard Ratio			(1.029, 6.610)
	Eribulin	Number of Patients	105	106	
		Patients With Events (%)	63 (60.0)	33 (31.1)	
		Patients Without Events (Censored) (%)	42 (40.0)	73 (68.9)	
		Median Time (months) [a]	2.0	9.8	
		95% CI	(1.5, 3.8)	(5.9, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.682
		95% CI for Hazard Ratio			(1.756, 4.097)
	Vinorelbine	Number of Patients	47	38	
		Patients With Events (%)	28 (59.6)	14 (36.8)	
		Patients Without Events (Censored) (%)	19 (40.4)	24 (63.2)	
		Median Time (months) [a]	3.0	5.1	
		95% CI	(1.5, 5.4)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.5622
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.211
		95% CI for Hazard Ratio			(0.630, 2.326)
		P-value of Subgroup*Treatment Interaction [d]			0.1344

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Financial Difficulties	Capecitabine	Number of Patients	18	18	
		Patients With Events (%)	3 (16.7)	4 (22.2)	
		Patients Without Events (Censored) (%)	15 (83.3)	14 (77.8)	
		Median Time (months) [a]	18.2	NE	
		95% CI	(NE, NE)	(3.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.3841
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.480
		95% CI for Hazard Ratio			(0.088, 2.625)
	Eribulin	Number of Patients	104	103	
		Patients With Events (%)	33 (31.7)	20 (19.4)	
		Patients Without Events (Censored) (%)	71 (68.3)	83 (80.6)	
		Median Time (months) [a]	NE	NE	
		95% CI	(6.5, NE)	(8.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.1089
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.568
		95% CI for Hazard Ratio			(0.899, 2.733)
	Vinorelbine	Number of Patients	47	38	
		Patients With Events (%)	7 (14.9)	7 (18.4)	
		Patients Without Events (Censored) (%)	40 (85.1)	31 (81.6)	
		Median Time (months) [a]	NE	6.7	
		95% CI	(NE, NE)	(3.7, NE)	
		Log-rank p-value (Unstratified) [b]			0.1937
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.493
		95% CI for Hazard Ratio			(0.166, 1.465)
		P-value of Subgroup*Treatment Interaction [d]			0.1201

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.12
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Investigators choice of chemotherapy prior to randomizaion
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Capecitabine	Number of Patients	20	20	
		Patients With Events (%)	7 (35.0)	11 (55.0)	
		Patients Without Events (Censored) (%)	13 (65.0)	9 (45.0)	
		Median Time (months) [a]	NE	3.0	
		95% CI	(2.8, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.2006
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.542
		95% CI for Hazard Ratio			(0.209, 1.405)
	Eribulin	Number of Patients	107	107	
		Patients With Events (%)	55 (51.4)	51 (47.7)	
		Patients Without Events (Censored) (%)	52 (48.6)	56 (52.3)	
		Median Time (months) [a]	4.3	7.2	
		95% CI	(2.5, 9.2)	(4.3, 9.9)	
		Log-rank p-value (Unstratified) [b]			0.5965
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.108
		95% CI for Hazard Ratio			(0.756, 1.623)
	Vinorelbine	Number of Patients	47	38	
		Patients With Events (%)	23 (48.9)	17 (44.7)	
		Patients Without Events (Censored) (%)	24 (51.1)	21 (55.3)	
		Median Time (months) [a]	6.5	3.7	
		95% CI	(3.7, 23.6)	(1.4, 5.1)	
		Log-rank p-value (Unstratified) [b]			0.0035
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.355
		95% CI for Hazard Ratio			(0.172, 0.732)
		P-value of Subgroup*Treatment Interaction [d]			0.0606

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Global Health Status / QoL	Yes	Number of Patients	151	144	
		Patients With Events (%)	84 (55.6)	90 (62.5)	
		Patients Without Events (Censored) (%)	67 (44.4)	54 (37.5)	
		Median Time (months) [a]	4.4	2.8	
		95% CI	(2.9, 6.6)	(2.1, 3.7)	
		Log-rank p-value (Unstratified) [b]			0.0112
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.681
		95% CI for Hazard Ratio			(0.504, 0.920)
	No	Number of Patients	22	20	
		Patients With Events (%)	11 (50.0)	13 (65.0)	
		Patients Without Events (Censored) (%)	11 (50.0)	7 (35.0)	
		Median Time (months) [a]	13.6	2.0	
		95% CI	(1.0, NE)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.2819
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.645
		95% CI for Hazard Ratio			(0.286, 1.453)
		P-value of Subgroup*Treatment Interaction [d]			0.6731
Physical Functioning	Yes	Number of Patients	152	144	
		Patients With Events (%)	78 (51.3)	77 (53.5)	
		Patients Without Events (Censored) (%)	74 (48.7)	67 (46.5)	
		Median Time (months) [a]	4.7	3.4	
		95% CI	(2.9, 7.1)	(2.2, 4.9)	
		Log-rank p-value (Unstratified) [b]			0.1251
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.782
		95% CI for Hazard Ratio			(0.570, 1.073)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	22	20	
		Patients With Events (%)	10 (45.5)	10 (50.0)	
		Patients Without Events (Censored) (%)	12 (54.5)	10 (50.0)	
		Median Time (months) [a]	12.5	2.6	
		95% CI	(1.4, NE)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.2514
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.598
		95% CI for Hazard Ratio			(0.245, 1.461)
		P-value of Subgroup*Treatment Interaction [d]			0.4378
Role Functioning	Yes	Number of Patients	149	139	
		Patients With Events (%)	99 (66.4)	86 (61.9)	
		Patients Without Events (Censored) (%)	50 (33.6)	53 (38.1)	
		Median Time (months) [a]	2.6	2.8	
		95% CI	(1.7, 4.2)	(1.7, 3.4)	
		Log-rank p-value (Unstratified) [b]			0.5316
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.912
		95% CI for Hazard Ratio			(0.682, 1.219)
	No	Number of Patients	22	20	
		Patients With Events (%)	12 (54.5)	16 (80.0)	
		Patients Without Events (Censored) (%)	10 (45.5)	4 (20.0)	
		Median Time (months) [a]	4.9	1.1	
		95% CI	(1.4, NE)	(0.8, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.0085
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.373
		95% CI for Hazard Ratio			(0.170, 0.819)
		P-value of Subgroup*Treatment Interaction [d]			0.0051

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Emotional Functioning	Yes	Number of Patients	147	145	
		Patients With Events (%)	54 (36.7)	66 (45.5)	
		Patients Without Events (Censored) (%)	93 (63.3)	79 (54.5)	
		Median Time (months) [a]	NE	4.5	
		95% CI	(5.1, NE)	(3.3, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.0373
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.685
		95% CI for Hazard Ratio			(0.477, 0.981)
	No	Number of Patients	22	19	
		Patients With Events (%)	7 (31.8)	9 (47.4)	
		Patients Without Events (Censored) (%)	15 (68.2)	10 (52.6)	
		Median Time (months) [a]	NE	4.5	
		95% CI	(2.8, NE)	(1.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.1013
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.431
		95% CI for Hazard Ratio			(0.152, 1.221)
		P-value of Subgroup*Treatment Interaction [d]			0.4193
Cognitive Functioning	Yes	Number of Patients	152	144	
		Patients With Events (%)	79 (52.0)	56 (38.9)	
		Patients Without Events (Censored) (%)	73 (48.0)	88 (61.1)	
		Median Time (months) [a]	4.0	7.2	
		95% CI	(2.8, 7.6)	(4.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.3197
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.190
		95% CI for Hazard Ratio			(0.843, 1.681)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	22	20	
		Patients With Events (%)	7 (31.8)	11 (55.0)	
		Patients Without Events (Censored) (%)	15 (68.2)	9 (45.0)	
		Median Time (months) [a]	NE	2.2	
		95% CI	(2.8, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.0662
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.420
		95% CI for Hazard Ratio			(0.161, 1.096)
		P-value of Subgroup*Treatment Interaction [d]			0.0299
Social Functioning	Yes	Number of Patients	148	138	
		Patients With Events (%)	89 (60.1)	76 (55.1)	
		Patients Without Events (Censored) (%)	59 (39.9)	62 (44.9)	
		Median Time (months) [a]	2.3	3.5	
		95% CI	(1.7, 4.3)	(2.7, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.7765
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.045
		95% CI for Hazard Ratio			(0.768, 1.422)
	No	Number of Patients	22	19	
		Patients With Events (%)	12 (54.5)	12 (63.2)	
		Patients Without Events (Censored) (%)	10 (45.5)	7 (36.8)	
		Median Time (months) [a]	3.1	2.6	
		95% CI	(1.7, NE)	(0.8, NE)	
		Log-rank p-value (Unstratified) [b]			0.3020
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.658
		95% CI for Hazard Ratio			(0.294, 1.473)
		P-value of Subgroup*Treatment Interaction [d]			0.2431

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Fatigue	Yes	Number of Patients	150	142	
		Patients With Events (%)	106 (70.7)	108 (76.1)	
		Patients Without Events (Censored) (%)	44 (29.3)	34 (23.9)	
		Median Time (months) [a]	2.0	1.3	
		95% CI	(1.5, 2.8)	(1.0, 1.9)	
		Log-rank p-value (Unstratified) [b]			0.0136
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.716
		95% CI for Hazard Ratio			(0.547, 0.938)
	No	Number of Patients	22	20	
		Patients With Events (%)	15 (68.2)	16 (80.0)	
		Patients Without Events (Censored) (%)	7 (31.8)	4 (20.0)	
		Median Time (months) [a]	2.3	1.0	
		95% CI	(0.9, 16.2)	(0.8, 2.2)	
		Log-rank p-value (Unstratified) [b]			0.0952
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.553
		95% CI for Hazard Ratio			(0.267, 1.145)
		P-value of Subgroup*Treatment Interaction [d]			0.4132
Nausea and Vomiting	Yes	Number of Patients	151	145	
		Patients With Events (%)	93 (61.6)	68 (46.9)	
		Patients Without Events (Censored) (%)	58 (38.4)	77 (53.1)	
		Median Time (months) [a]	2.1	6.1	
		95% CI	(1.5, 4.1)	(2.8, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.1389
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.265
		95% CI for Hazard Ratio			(0.923, 1.735)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	22	20	
		Patients With Events (%)	13 (59.1)	9 (45.0)	
		Patients Without Events (Censored) (%)	9 (40.9)	11 (55.0)	
		Median Time (months) [a]	2.6	4.6	
		95% CI	(1.0, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.6525
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.213
		95% CI for Hazard Ratio			(0.517, 2.847)
		P-value of Subgroup*Treatment Interaction [d]			0.8184
Pain	Yes	Number of Patients	148	139	
		Patients With Events (%)	84 (56.8)	81 (58.3)	
		Patients Without Events (Censored) (%)	64 (43.2)	58 (41.7)	
		Median Time (months) [a]	3.8	3.1	
		95% CI	(2.8, 5.9)	(2.2, 4.3)	
		Log-rank p-value (Unstratified) [b]			0.2373
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.833
		95% CI for Hazard Ratio			(0.613, 1.132)
	No	Number of Patients	21	20	
		Patients With Events (%)	11 (52.4)	9 (45.0)	
		Patients Without Events (Censored) (%)	10 (47.6)	11 (55.0)	
		Median Time (months) [a]	9.7	8.2	
		95% CI	(1.4, NE)	(1.1, NE)	
		Log-rank p-value (Unstratified) [b]			0.9936
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.996
		95% CI for Hazard Ratio			(0.407, 2.437)
		P-value of Subgroup*Treatment Interaction [d]			0.9537

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Dyspnea	Yes	Number of Patients	148	142	
		Patients With Events (%)	69 (46.6)	73 (51.4)	
		Patients Without Events (Censored) (%)	79 (53.4)	69 (48.6)	
		Median Time (months) [a]	5.9	3.9	
		95% CI	(4.3, 9.5)	(2.7, 7.7)	
		Log-rank p-value (Unstratified) [b]			0.0598
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.729
		95% CI for Hazard Ratio			(0.523, 1.016)
	No	Number of Patients	22	19	
		Patients With Events (%)	9 (40.9)	11 (57.9)	
		Patients Without Events (Censored) (%)	13 (59.1)	8 (42.1)	
		Median Time (months) [a]	8.3	3.2	
		95% CI	(3.1, NE)	(1.0, NE)	
		Log-rank p-value (Unstratified) [b]			0.0483
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.403
		95% CI for Hazard Ratio			(0.158, 1.026)
		P-value of Subgroup*Treatment Interaction [d]			0.2233
Insomnia	Yes	Number of Patients	139	132	
		Patients With Events (%)	56 (40.3)	58 (43.9)	
		Patients Without Events (Censored) (%)	83 (59.7)	74 (56.1)	
		Median Time (months) [a]	8.7	4.3	
		95% CI	(6.0, 23.6)	(2.2, NE)	
		Log-rank p-value (Unstratified) [b]			0.0383
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.678
		95% CI for Hazard Ratio			(0.467, 0.984)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	21	18	
		Patients With Events (%)	12 (57.1)	11 (61.1)	
		Patients Without Events (Censored) (%)	9 (42.9)	7 (38.9)	
		Median Time (months) [a]	4.7	3.2	
		95% CI	(2.6, NE)	(1.4, 7.4)	
		Log-rank p-value (Unstratified) [b]			0.1958
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.579
		95% CI for Hazard Ratio			(0.247, 1.356)
		P-value of Subgroup*Treatment Interaction [d]			0.9804
Appetite Loss	Yes	Number of Patients	145	138	
		Patients With Events (%)	85 (58.6)	65 (47.1)	
		Patients Without Events (Censored) (%)	60 (41.4)	73 (52.9)	
		Median Time (months) [a]	3.3	4.4	
		95% CI	(1.7, 5.5)	(2.3, 9.6)	
		Log-rank p-value (Unstratified) [b]			0.4266
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.140
		95% CI for Hazard Ratio			(0.823, 1.578)
	No	Number of Patients	22	18	
		Patients With Events (%)	12 (54.5)	13 (72.2)	
		Patients Without Events (Censored) (%)	10 (45.5)	5 (27.8)	
		Median Time (months) [a]	6.7	3.5	
		95% CI	(0.8, NE)	(1.0, 5.6)	
		Log-rank p-value (Unstratified) [b]			0.3862
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.708
		95% CI for Hazard Ratio			(0.320, 1.567)
		P-value of Subgroup*Treatment Interaction [d]			0.2818

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Constipation	Yes	Number of Patients	149	139	
		Patients With Events (%)	74 (49.7)	58 (41.7)	
		Patients Without Events (Censored) (%)	75 (50.3)	81 (58.3)	
		Median Time (months) [a]	4.6	4.9	
		95% CI	(2.5, 9.1)	(3.5, NE)	
		Log-rank p-value (Unstratified) [b]			0.3073
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.195
		95% CI for Hazard Ratio			(0.847, 1.686)
	No	Number of Patients	21	19	
		Patients With Events (%)	9 (42.9)	12 (63.2)	
		Patients Without Events (Censored) (%)	12 (57.1)	7 (36.8)	
		Median Time (months) [a]	13.9	1.9	
		95% CI	(2.3, NE)	(0.9, NE)	
		Log-rank p-value (Unstratified) [b]			0.0215
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.364
		95% CI for Hazard Ratio			(0.146, 0.906)
		P-value of Subgroup*Treatment Interaction [d]			0.0109
Diarrhea	Yes	Number of Patients	150	144	
		Patients With Events (%)	89 (59.3)	51 (35.4)	
		Patients Without Events (Censored) (%)	61 (40.7)	93 (64.6)	
		Median Time (months) [a]	2.1	7.7	
		95% CI	(1.6, 3.8)	(5.3, NE)	
		Log-rank p-value (Unstratified) [b]			<.0001
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			2.064
		95% CI for Hazard Ratio			(1.461, 2.915)

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
	No	Number of Patients	22	20	
		Patients With Events (%)	15 (68.2)	4 (20.0)	
		Patients Without Events (Censored) (%)	7 (31.8)	16 (80.0)	
		Median Time (months) [a]	1.7	NE	
		95% CI	(0.8, 4.4)	(5.6, NE)	
		Log-rank p-value (Unstratified) [b]			0.0020
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			4.779
		95% CI for Hazard Ratio			(1.578, 14.474)
		P-value of Subgroup*Treatment Interaction [d]			0.1438
Financial Difficulties	Yes	Number of Patients	147	141	
		Patients With Events (%)	38 (25.9)	24 (17.0)	
		Patients Without Events (Censored) (%)	109 (74.1)	117 (83.0)	
		Median Time (months) [a]	NE	NE	
		95% CI	(18.2, NE)	(NE, NE)	
		Log-rank p-value (Unstratified) [b]			0.2397
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			1.358
		95% CI for Hazard Ratio			(0.813, 2.270)
	No	Number of Patients	22	18	
		Patients With Events (%)	5 (22.7)	7 (38.9)	
		Patients Without Events (Censored) (%)	17 (77.3)	11 (61.1)	
		Median Time (months) [a]	NE	5.0	
		95% CI	(5.8, NE)	(1.4, NE)	
		Log-rank p-value (Unstratified) [b]			0.1006
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.394
		95% CI for Hazard Ratio			(0.124, 1.253)
		P-value of Subgroup*Treatment Interaction [d]			0.0594

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

Table 15.15.7.1.13
Summary of Time to First HRQoL Worsening with Death Being Censored for EORTC QLQ-C30 by Subgroup - Baseline documented target or non-target liver lesions
EORTC QLQ-C30 Evaluable Population
Excluding Subjects for whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded

Domain	Subgroup	Statistic	SG (N=174)	TPC (N=165)	Treatment Comparison
Summary Score	Yes	Number of Patients	152	145	
		Patients With Events (%)	75 (49.3)	67 (46.2)	
		Patients Without Events (Censored) (%)	77 (50.7)	78 (53.8)	
		Median Time (months) [a]	5.5	5.1	
		95% CI	(3.7, 7.5)	(3.1, 9.5)	
		Log-rank p-value (Unstratified) [b]			0.6581
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.928
		95% CI for Hazard Ratio			(0.666, 1.292)
	No	Number of Patients	22	20	
		Patients With Events (%)	10 (45.5)	12 (60.0)	
		Patients Without Events (Censored) (%)	12 (54.5)	8 (40.0)	
		Median Time (months) [a]	8.3	3.5	
		95% CI	(1.7, NE)	(1.0, 11.4)	
		Log-rank p-value (Unstratified) [b]			0.1919
		Unstratified Cox Regression Analysis [c]			
		Hazard Ratio (Relative to TPC)			0.575
		95% CI for Hazard Ratio			(0.246, 1.341)
		P-value of Subgroup*Treatment Interaction [d]			0.2115

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

[a] Median Time is from Kaplan-Meier estimate.

[b] P-value is estimated from unstratified log-rank test.

[c] HR and 95% CI are estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC) as covariate.

[d] P-value is estimated using an unstratified Cox proportional hazards regression analysis with treatment arm (SG vs. TPC), subgroup, and treatment*subgroup as covariates.

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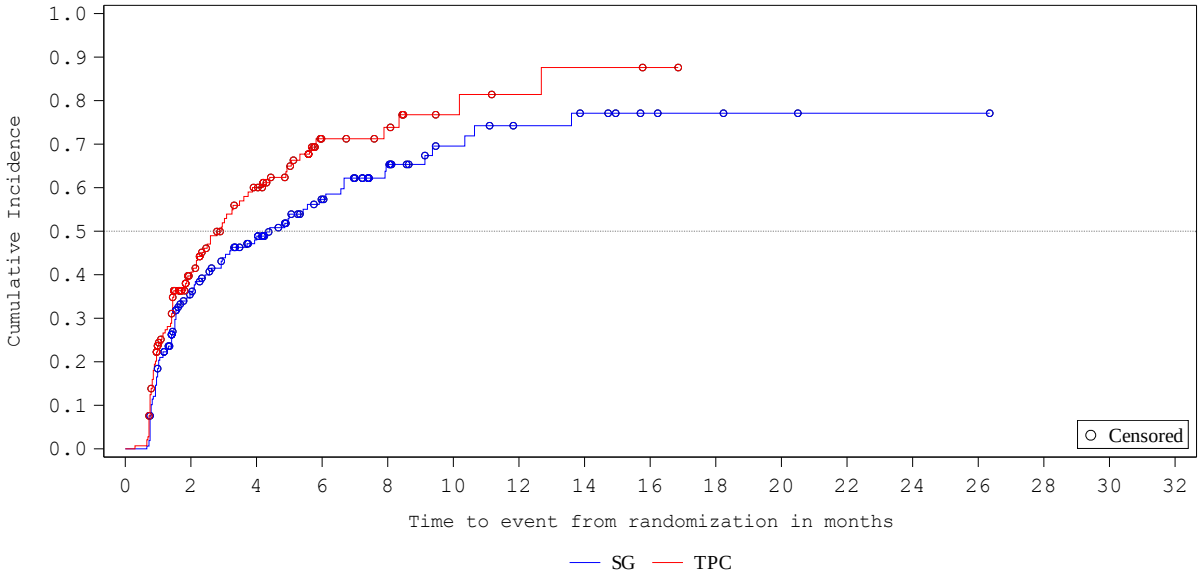
Figure 15.15.5.1.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
Endocrine therapy in the metastatic setting for at least 6 months = Yes
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**158**	**87**	**60**	**36**	**22**	**13**	**9**	**7**	**4**	**3**	**2**	**1**	**1**	**1**	**0**
TPC	**145**	**68**	**38**	**13**	**10**	**5**	**3**	**2**	**1**	**0**					

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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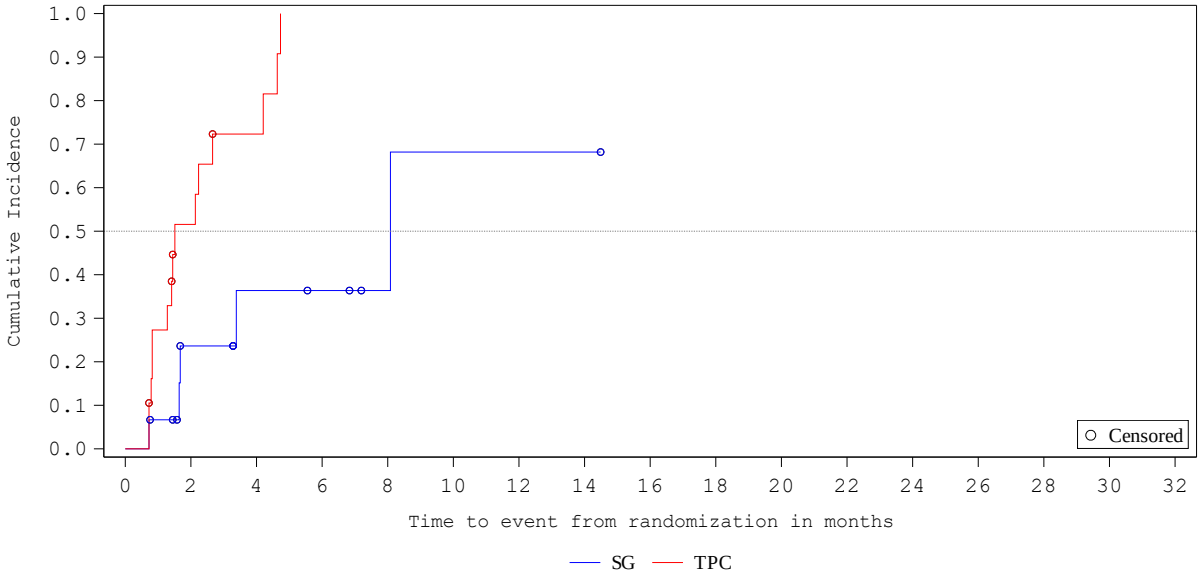
Figure 15.15.5.1.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
Endocrine therapy in the metastatic setting for at least 6 months = No
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	15	8	5	4	2	1	1	1	0
TPC	19	7	3	0					

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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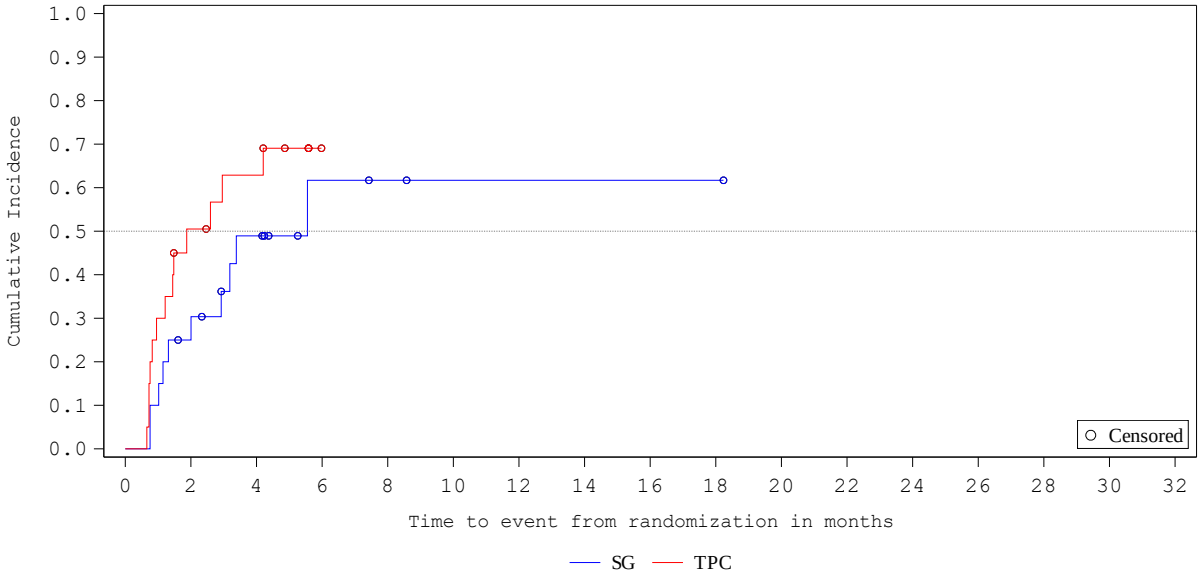
Figure 15.15.5.1.2.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Capecitabine
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	20	14	8	3	2	1	1	1	1	1	0
TPC	20	9	6	0							

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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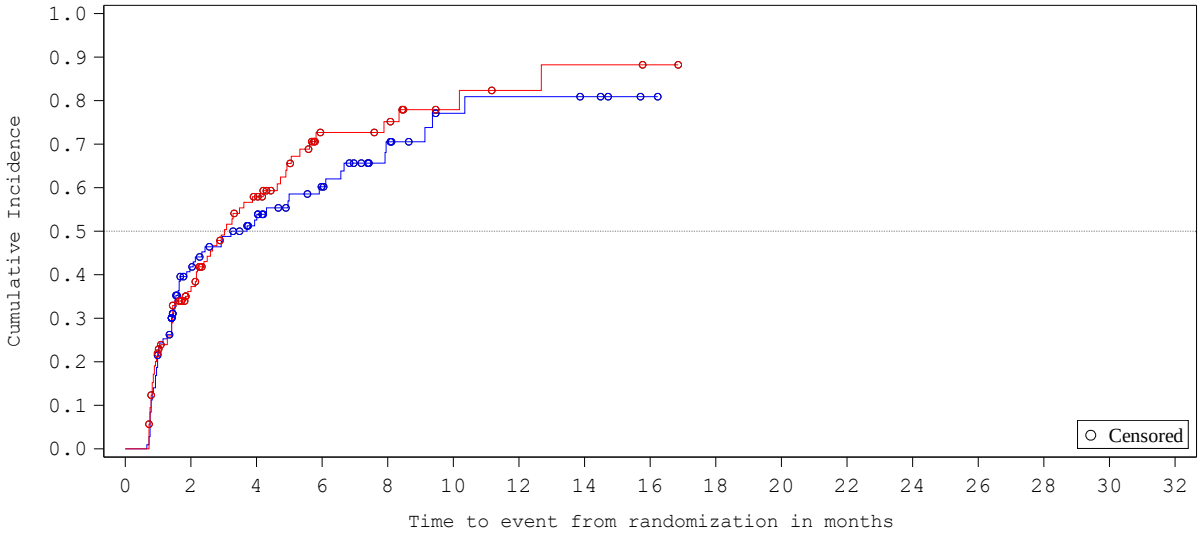
Figure 15.15.5.1.2.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Eribulin
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	107	52	36	23	12	6	5	4	1	0
TPC	106	57	32	12	10	5	3	2	1	0

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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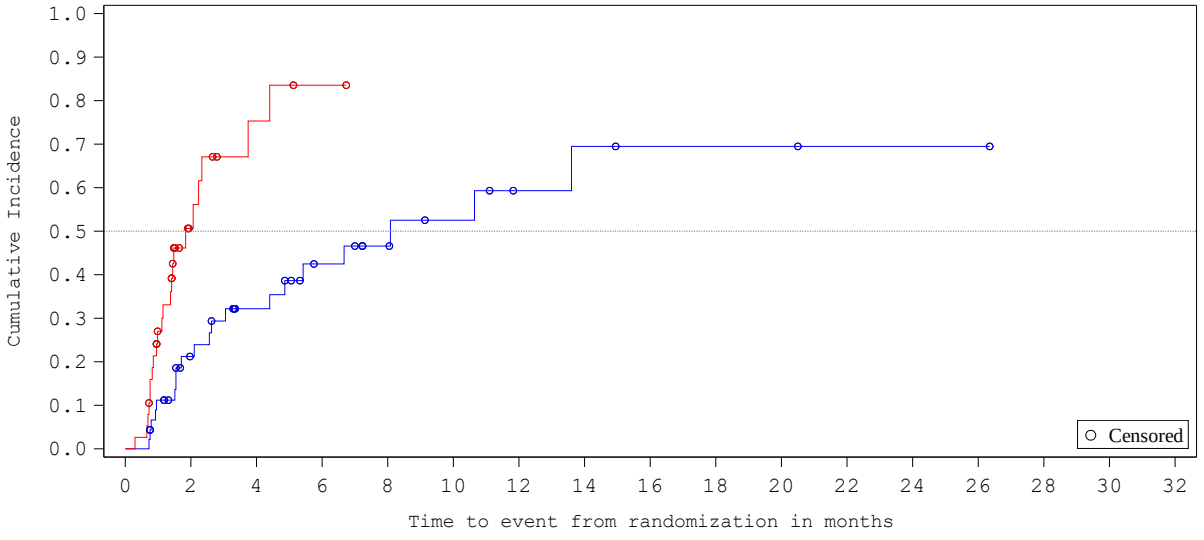
Figure 15.15.5.1.2.3
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Global Health Status/QoL by Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Vinorelbine
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	46	29	21	14	10	7	4	3	2	2	2	1	1	1	0
TPC	38	9	3	1	0										

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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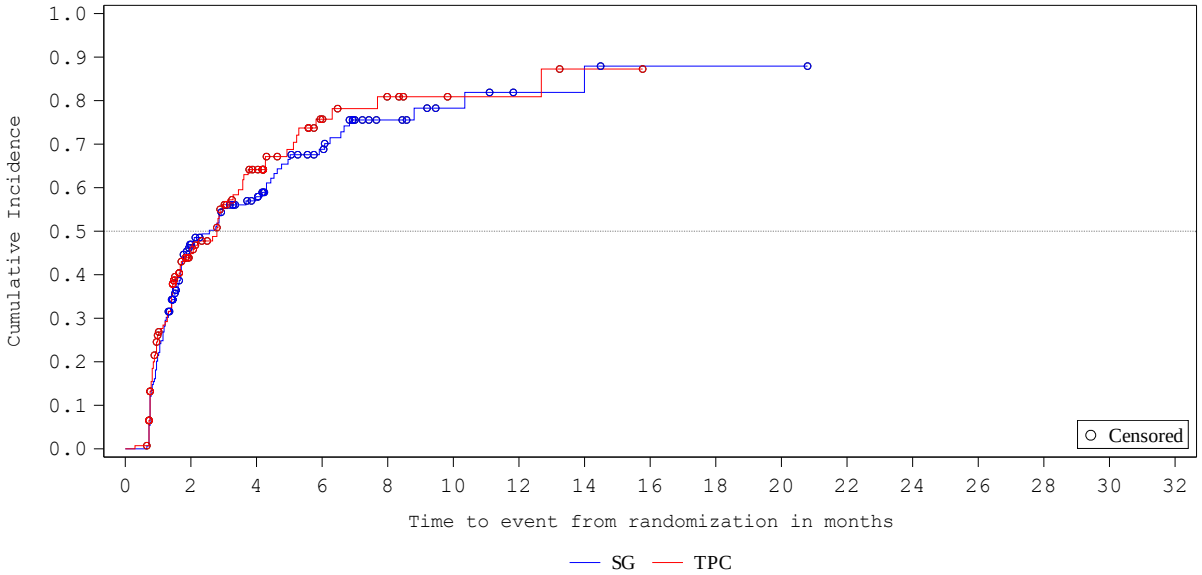
Figure 15.15.5.2.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Role Functioning by Treatment Group
Baseline documented target or non-target liver lesions = Yes
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**149**	**67**	**44**	**25**	**11**	**6**	**3**	**2**	**1**	**1**	**1**	**0**
TPC	**139**	**58**	**29**	**11**	**6**	**3**	**3**	**1**	**0**			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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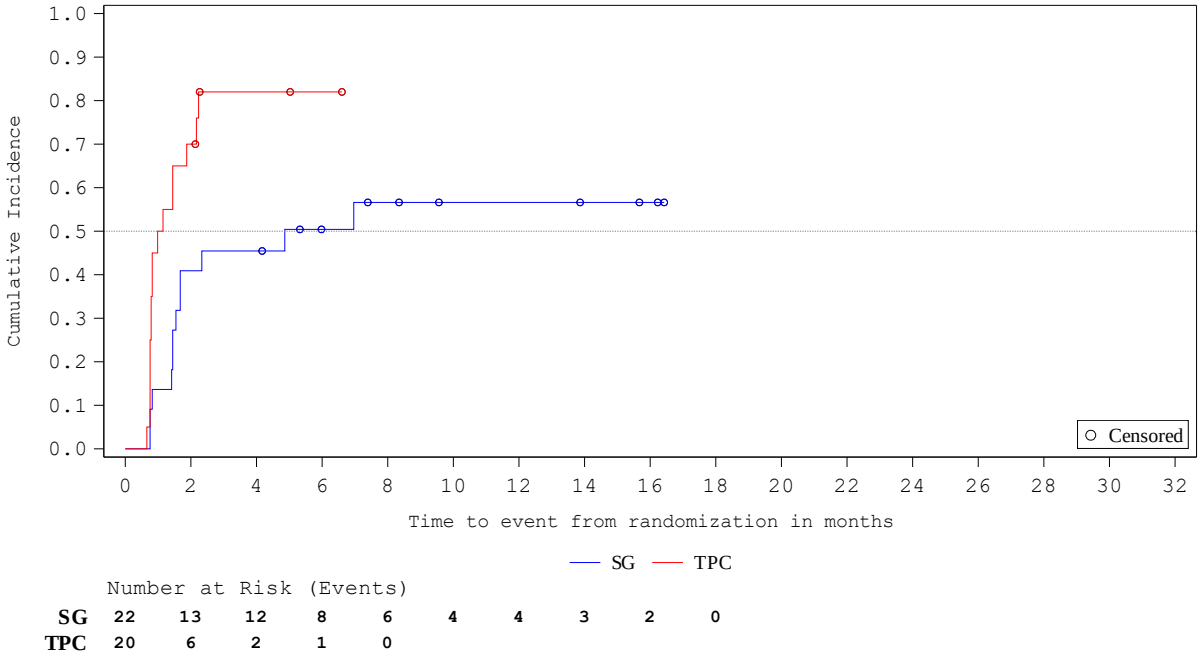
Figure 15.15.5.2.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Role Functioning by Treatment Group
Baseline documented target or non-target liver lesions = No
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**22**	**13**	**12**	**8**	**6**	**4**	**4**	**3**	**2**	**0**
TPC	**20**	**6**	**2**	**1**	**0**					

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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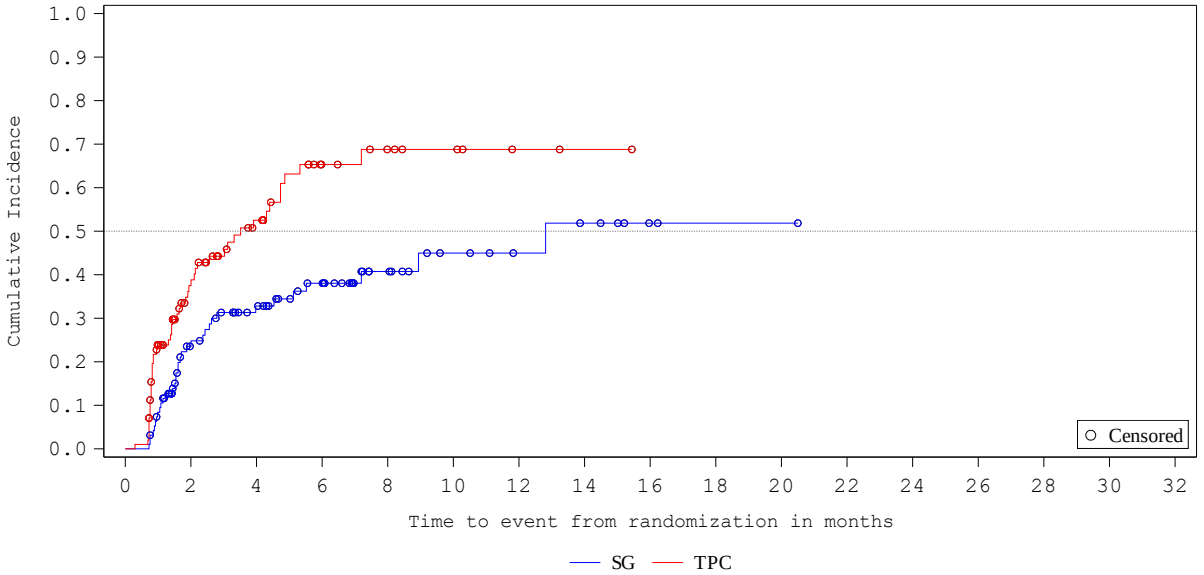
Figure 15.15.5.3.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Emotional Functioning by Treatment Group
Prior CDK inhibitor treatment duration ≤12 Months
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	96	60	45	33	18	11	8	6	2	1	1	0
TPC	99	47	27	11	7	5	2	1	0			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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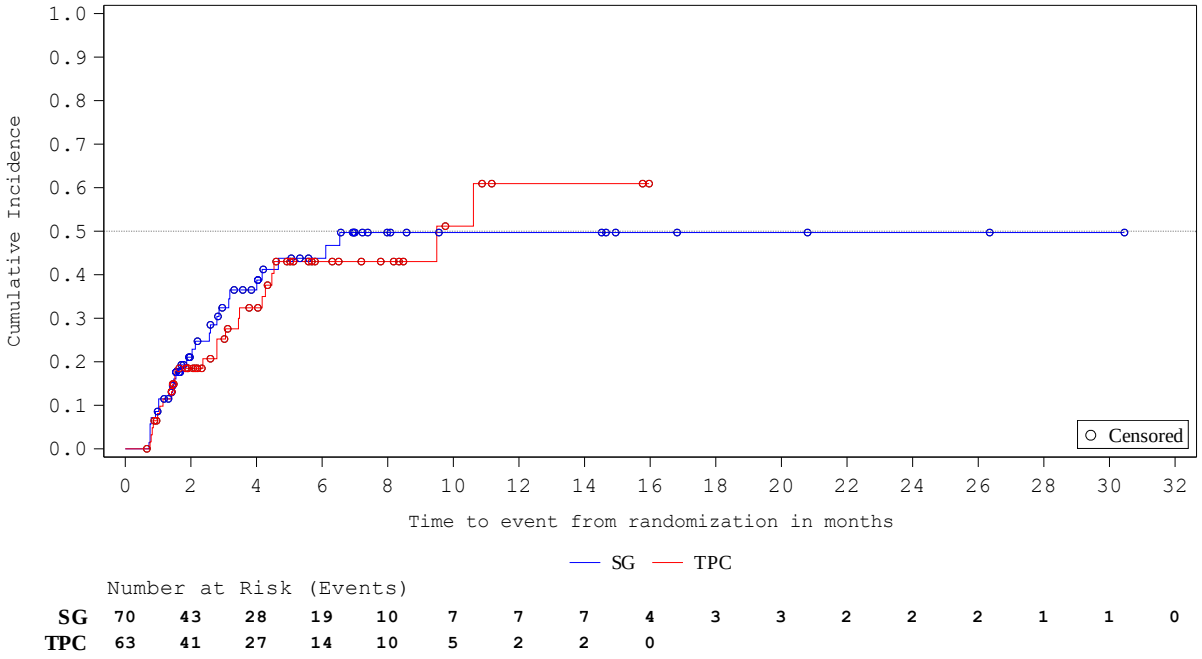
Figure 15.15.5.3.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Emotional Functioning by Treatment Group
Prior CDK inhibitor treatment duration >12 Months
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**70**	**43**	**28**	**19**	**10**	**7**	**7**	**7**	**4**	**3**	**3**	**2**	**2**	**2**	**1**	**1**	**0**
TPC	**63**	**41**	**27**	**14**	**10**	**5**	**2**	**2**	**0**								

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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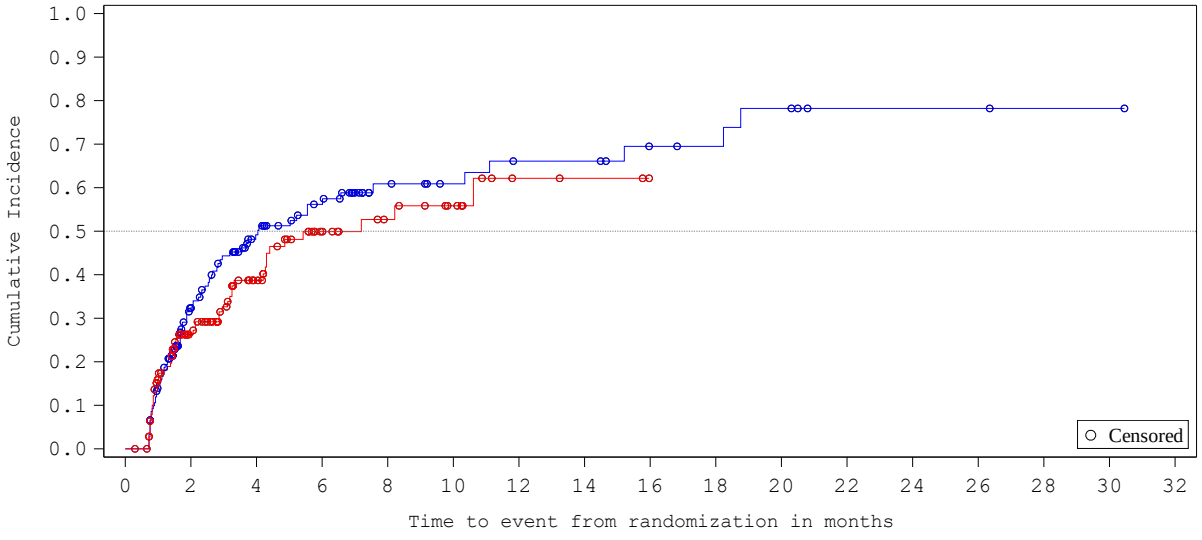
Figure 15.15.5.4.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Cognitive Functioning by Treatment Group
Baseline documented target or non-target liver lesions = Yes
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**152**	**82**	**49**	**34**	**19**	**15**	**12**	**12**	**8**	**7**	**5**	**2**	**2**	**2**	**1**	**1**	**0**
TPC	**144**	**76**	**43**	**22**	**15**	**10**	**3**	**2**	**0**								

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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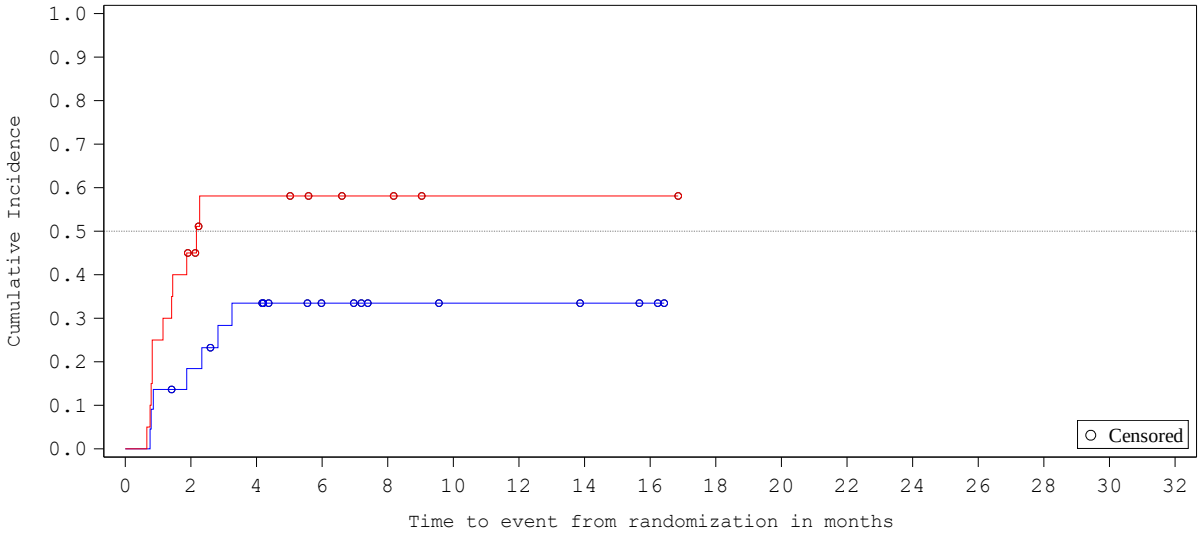
Figure 15.15.5.4.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Cognitive Functioning by Treatment Group
Baseline documented target or non-target liver lesions = No
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	22	17	13	8	5	4	4	3	2	0
TPC	20	10	6	4	3	1	1	1	1	0

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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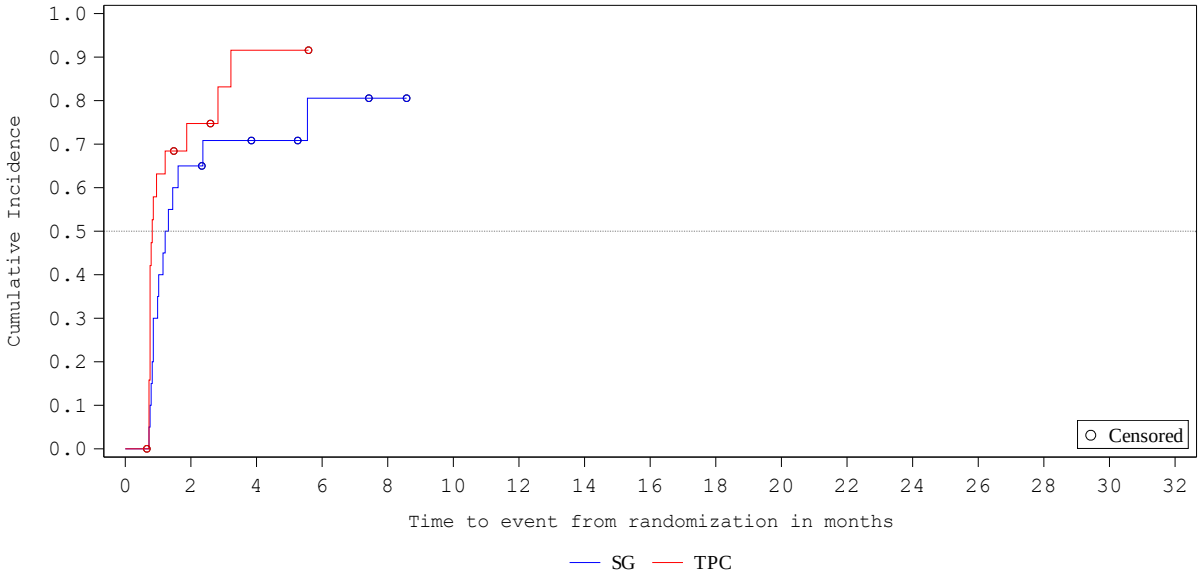
Figure 15.15.5.5.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Fatigueby Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Capecitabine
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	20	7	4	2	1	0
TPC	20	4	1	0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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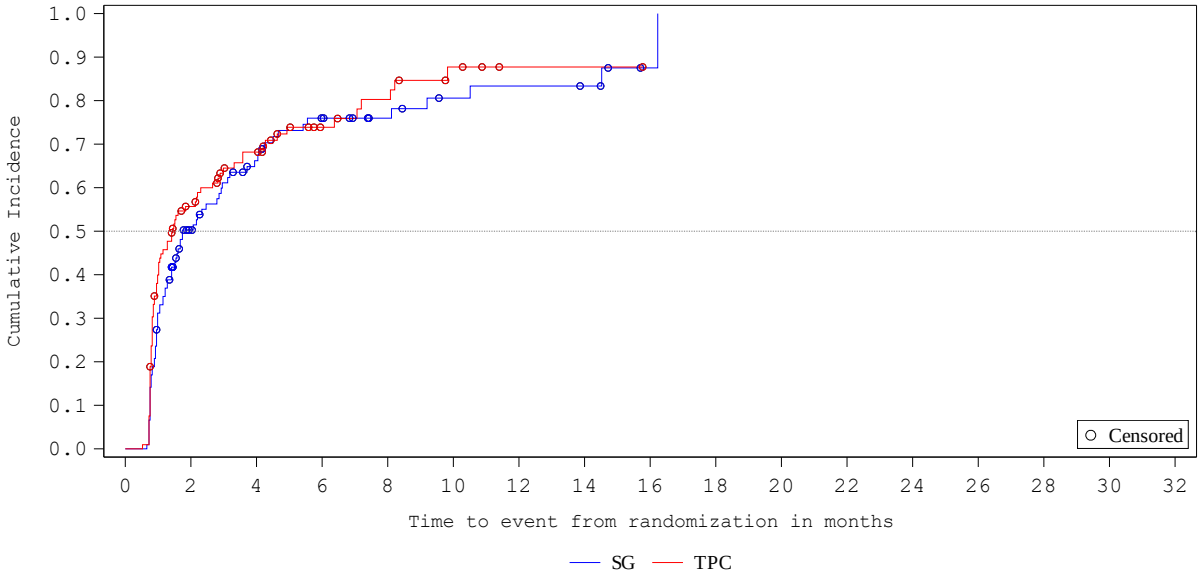
Figure 15.15.5.5.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Fatigueby Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Eribulin
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**106**	**43**	**25**	**16**	**11**	**7**	**6**	**5**	**1**	**0**
TPC	**106**	**42**	**26**	**13**	**9**	**4**	**1**	**1**	**0**	

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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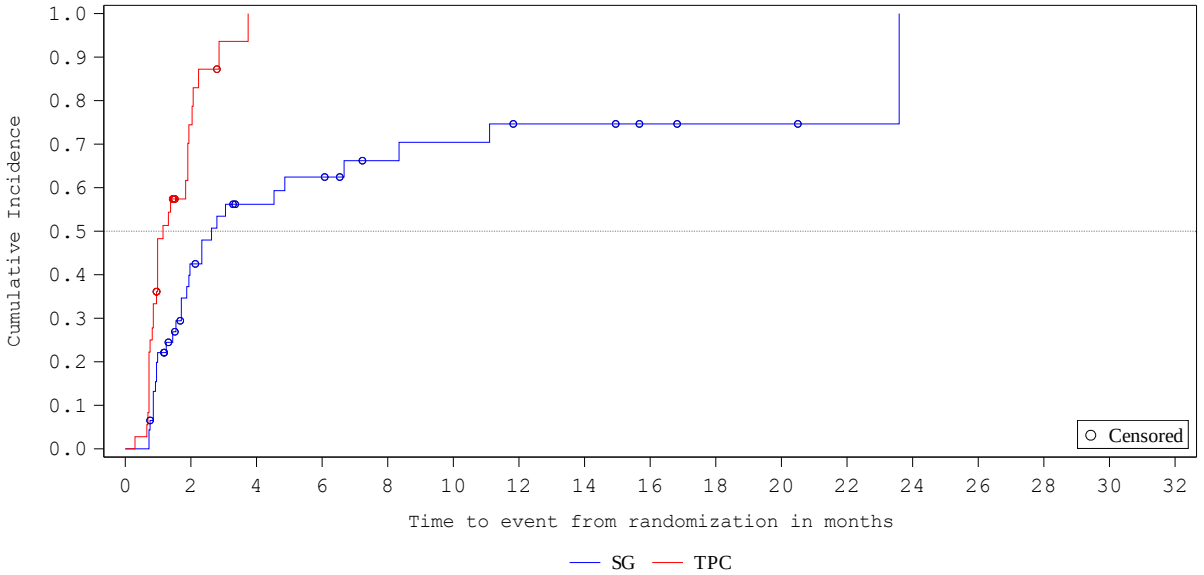
Figure 15.15.5.5.1.3
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Fatigueby Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Vinorelbine
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	46	22	14	12	8	7	5	5	3	2	2	1	0
TPC	36	6	0									

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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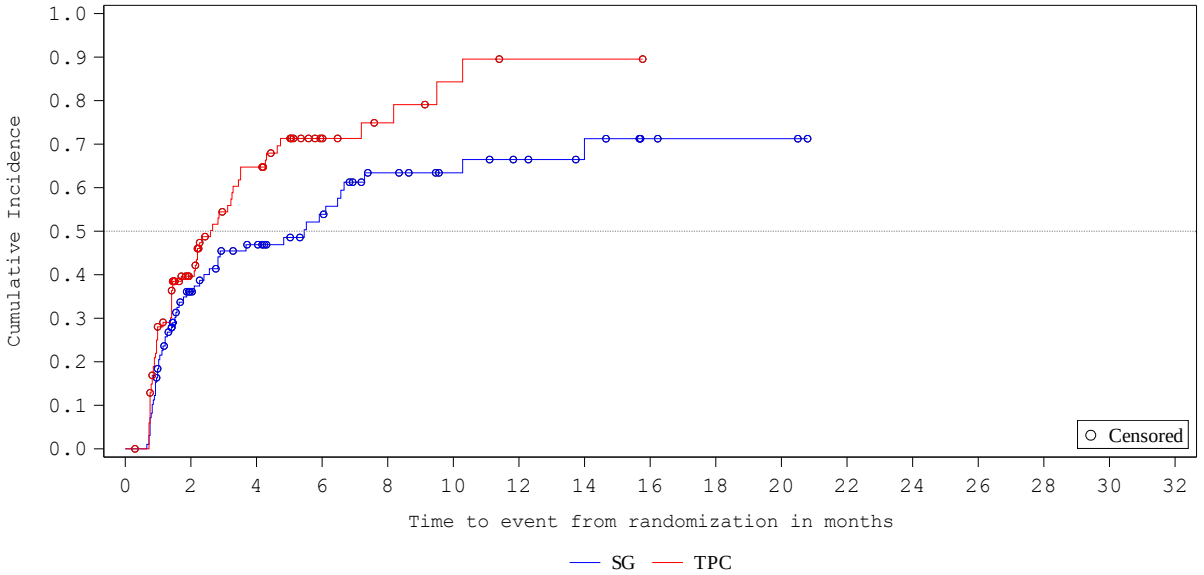
Figure 15.15.5.6.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Pain by Treatment Group
Chemotherapy in neo/adjuvant setting = Yes
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	98	50	36	26	16	12	9	6	3	2	2	0
TPC	102	48	24	10	6	3	1	1	0			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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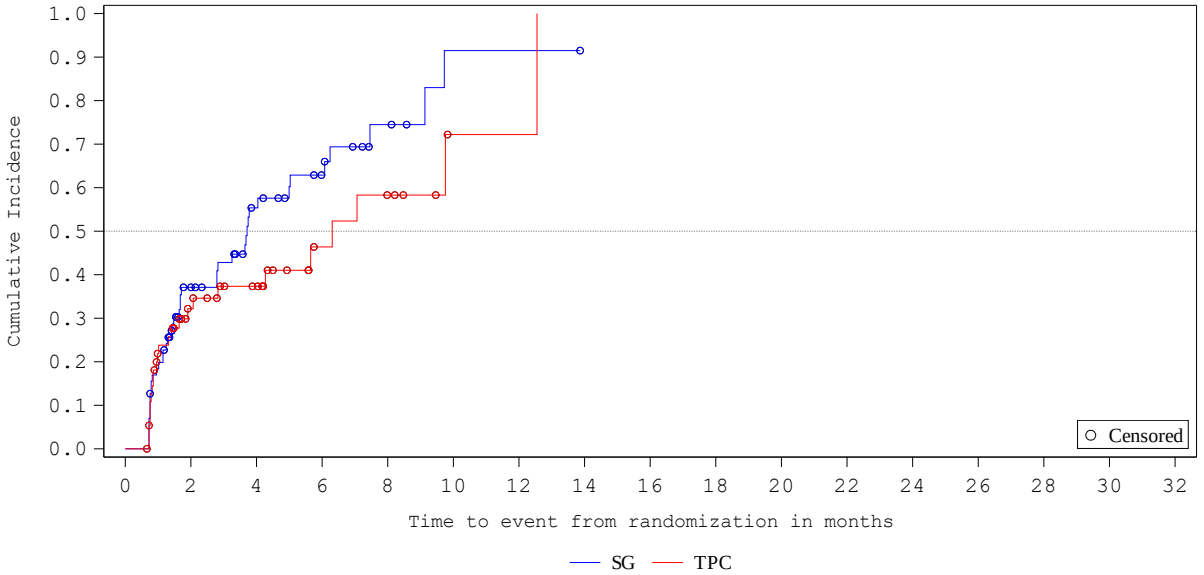
Figure 15.15.5.6.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Pain by Treatment Group
Chemotherapy in neo/adjuvant setting = No
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	71	36	20	12	5	1	1	0
TPC	57	28	20	9	6	1	1	0

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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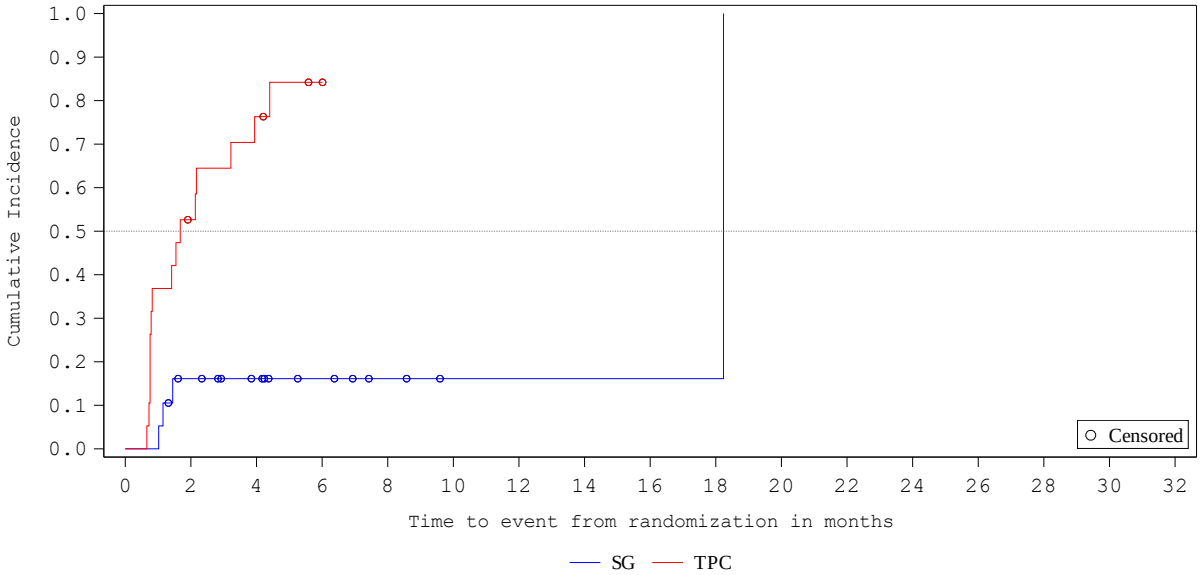
Figure 15.15.5.7.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Insomnia by Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Capecitabine
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	19	14	10	6	3	1	1	1	1	1	0
TPC	19	8	4	1	0						

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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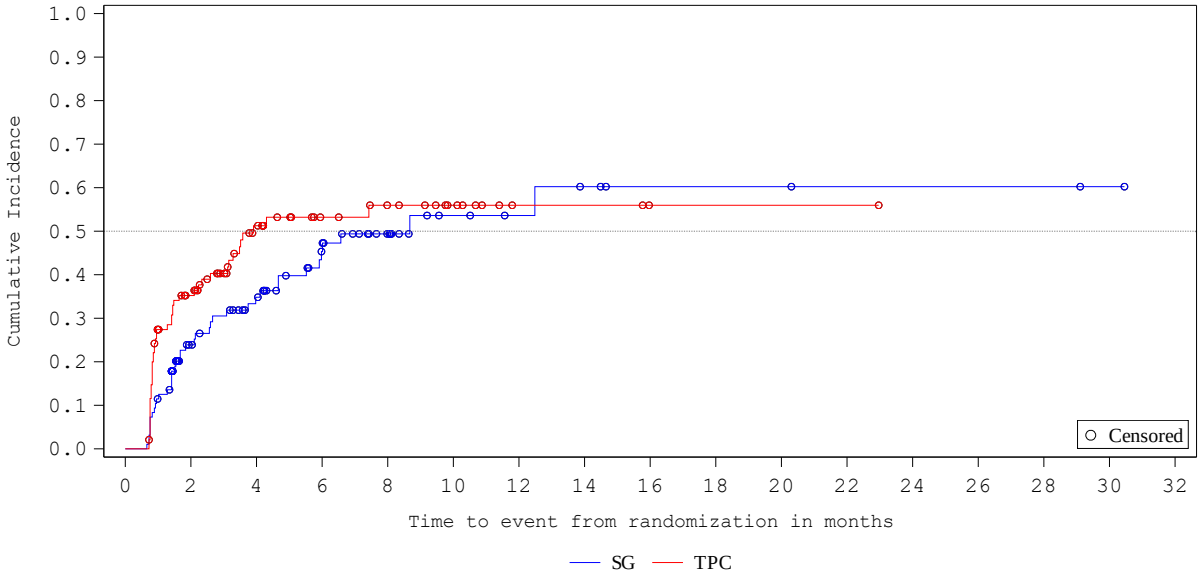
Figure 15.15.5.7.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Insomnia by Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Eribulin
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**96**	**59**	**44**	**28**	**17**	**9**	**7**	**5**	**3**	**3**	**3**	**2**	**2**	**2**	**2**	**1**	**0**
TPC	**96**	**55**	**29**	**18**	**14**	**9**	**3**	**3**	**1**	**1**	**1**	**1**	**0**				

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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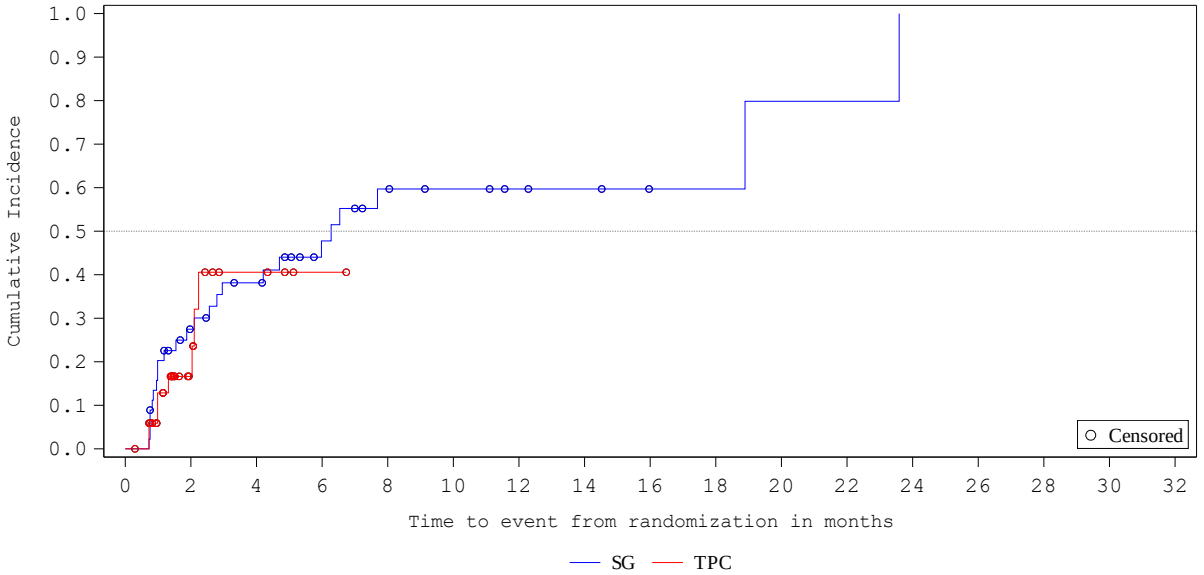
Figure 15.15.5.7.1.3
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Insomnia by Treatment Group
Investigators choice of chemotherapy prior to randomizaion = Vinorelbine
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**45**	**28**	**22**	**14**	**9**	**7**	**5**	**4**	**2**	**2**	**1**	**1**	**0**
TPC	**35**	**12**	**4**	**1**	**0**							

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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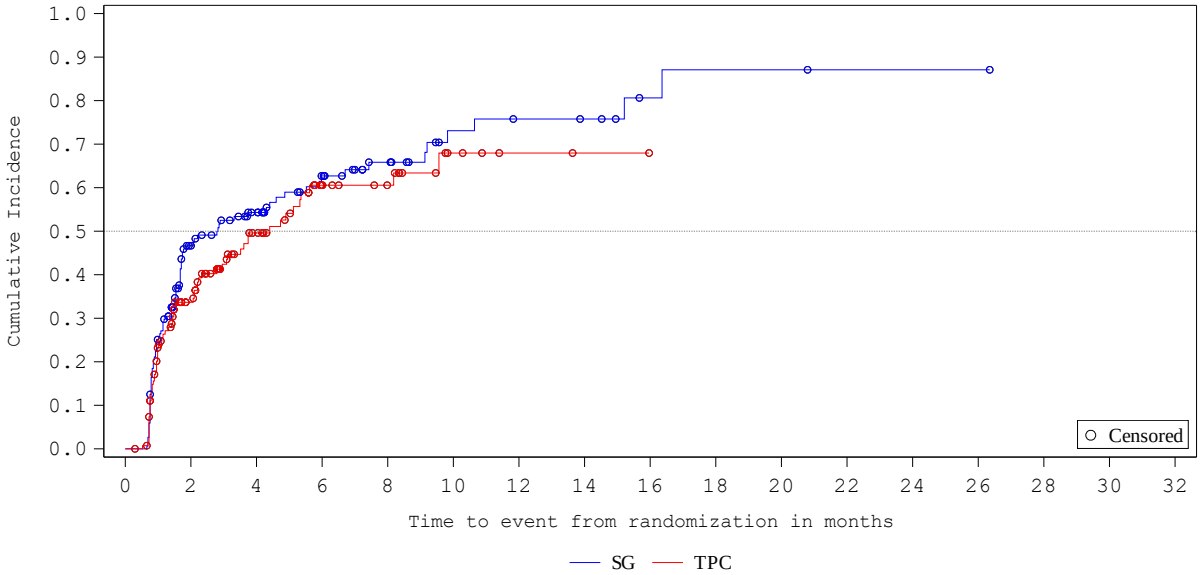
Figure 15.15.5.8.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Appetite Loss by Treatment Group
Endocrine therapy in the metastatic setting for at least 6 months = Yes
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**152**	**67**	**47**	**29**	**19**	**10**	**8**	**7**	**3**	**2**	**2**	**1**	**1**	**1**	**0**
TPC	**138**	**73**	**39**	**19**	**14**	**5**	**2**	**1**	**0**						

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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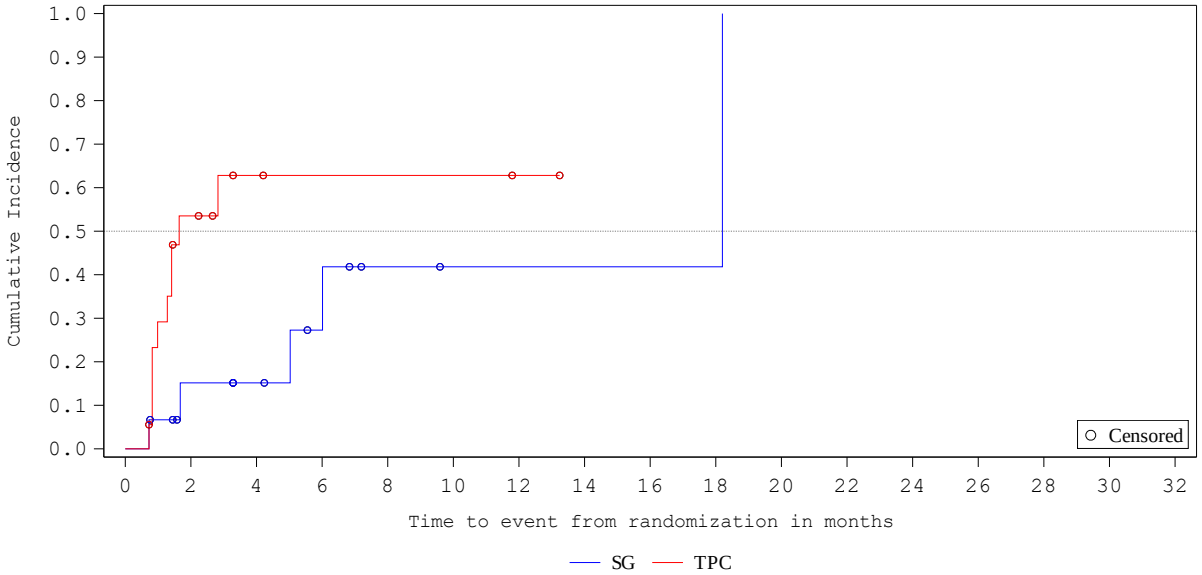
Figure 15.15.5.8.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Appetite Loss by Treatment Group
Endocrine therapy in the metastatic setting for at least 6 months = No
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	15	10	8	5	2	1	1	1	1	1	0
TPC	18	7	3	2	2	2	1	0			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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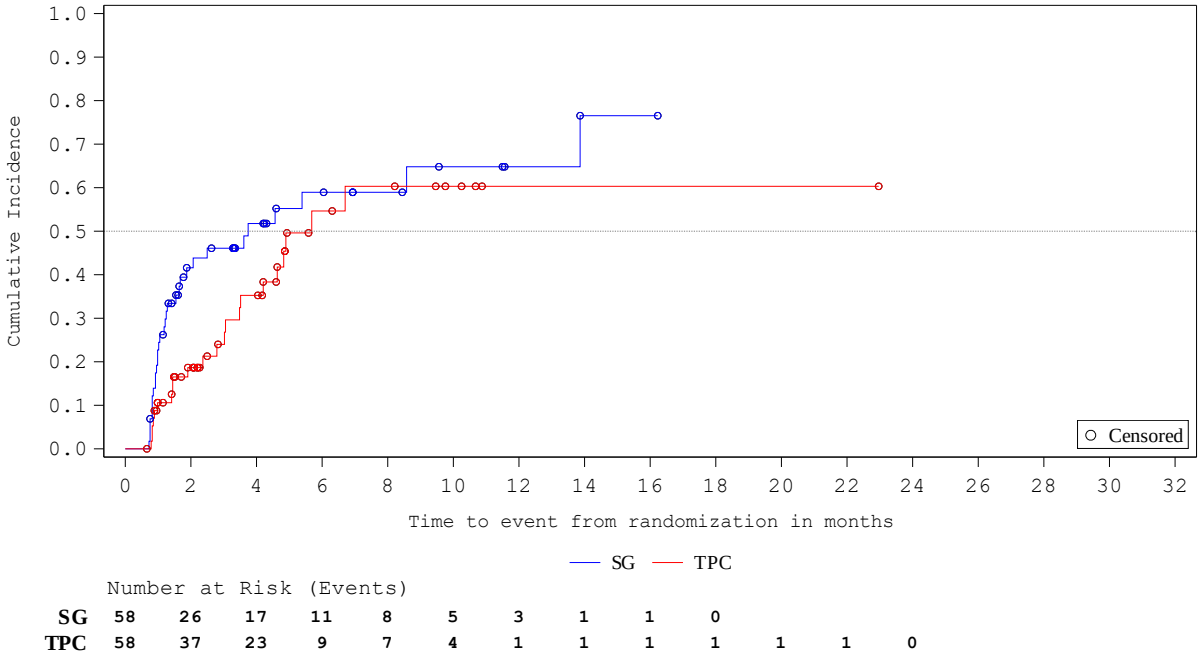
Figure 15.15.5.9.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Constipation by Treatment Group
Trop2 H-Score <100
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	58	26	17	11	8	5	3	1	1	0			
TPC	58	37	23	9	7	4	1	1	1	1	1	1	0

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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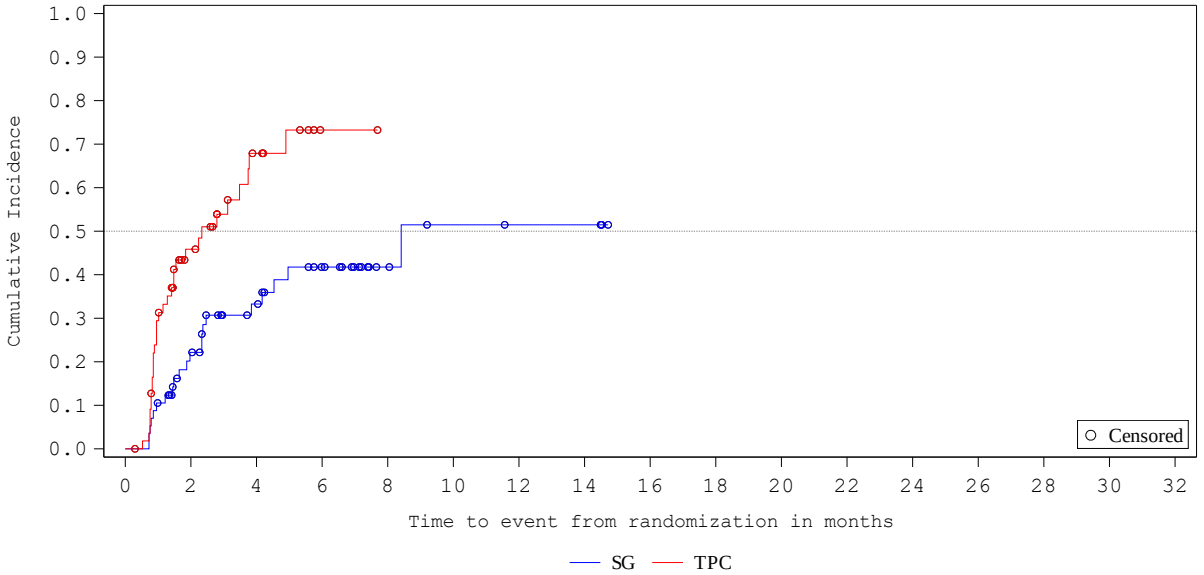
Figure 15.15.5.9.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Constipation by Treatment Group
Trop2 H-Score ≥100 to ≤200
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	57	39	26	17	7	4	3	3	0
TPC	56	22	8	1	0				

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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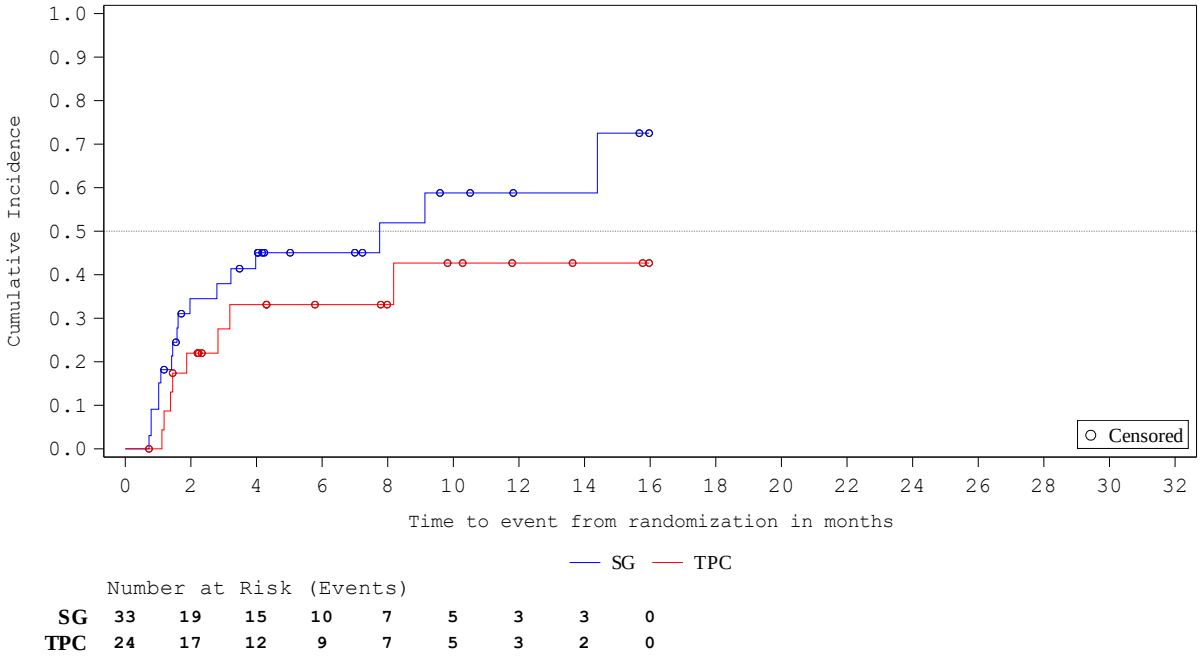
Figure 15.15.5.9.1.3
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Constipation by Treatment Group
Trop2 H-Score >200
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)									
SG	33	19	15	10	7	5	3	3	0
TPC	24	17	12	9	7	5	3	2	0

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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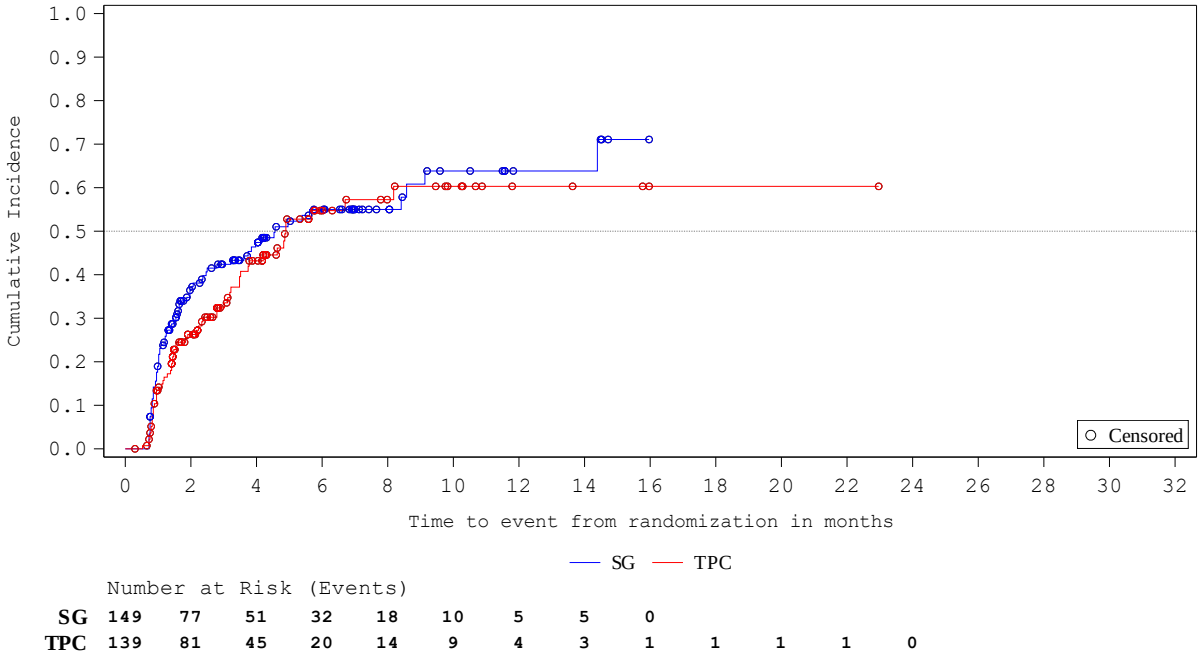
Figure 15.15.5.9.2.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Constipation by Treatment Group
Baseline documented target or non-target liver lesions = Yes
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	149	77	51	32	18	10	5	5	0				
TPC	139	81	45	20	14	9	4	3	1	1	1	1	0

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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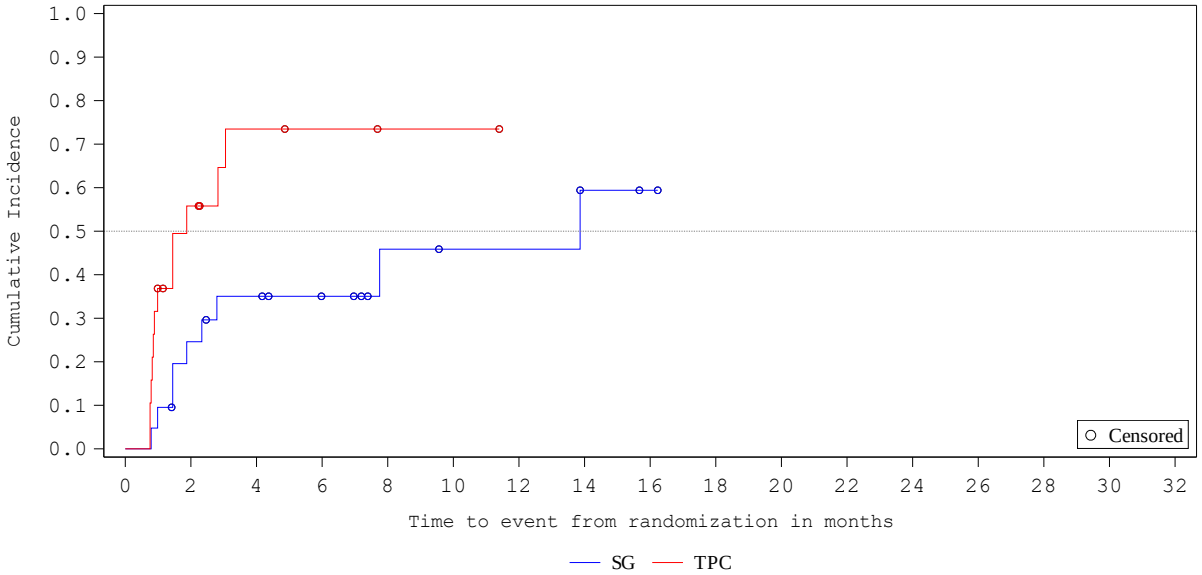
Figure 15.15.5.9.2.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Constipation by Treatment Group
Baseline documented target or non-target liver lesions = No
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**21**	**15**	**12**	**9**	**5**	**4**	**4**	**2**	**1**	**0**
TPC	**19**	**7**	**3**	**2**	**1**	**1**	**0**			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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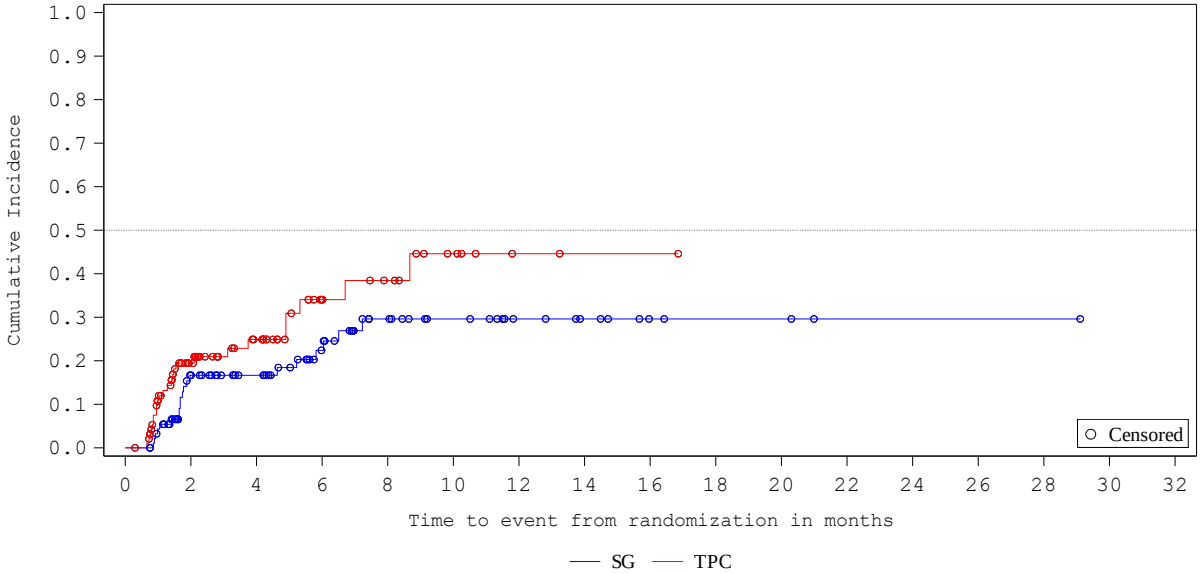
Figure 15.15.5.10.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Financial Difficulties by Treatment Group
Prior CDK inhibitor treatment duration ≤12 Months
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**95**	**64**	**52**	**36**	**23**	**17**	**11**	**8**	**4**	**3**	**3**	**1**	**1**	**1**	**1**	**0**
TPC	**97**	**55**	**35**	**16**	**12**	**6**	**2**	**1**	**1**	**0**						

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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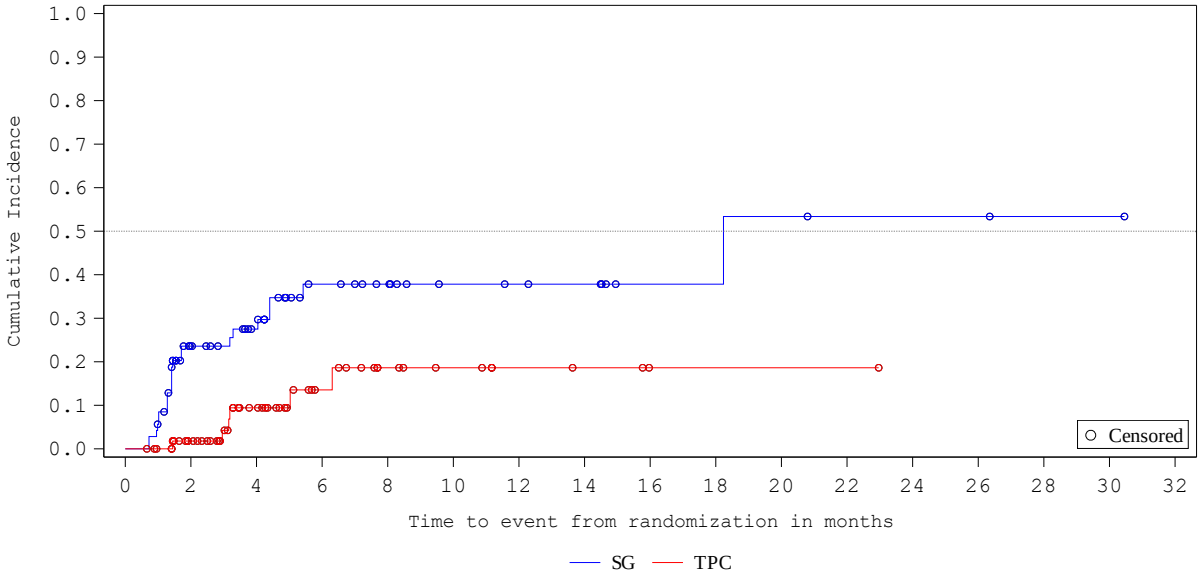
Figure 15.15.5.10.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Financial Difficulties by Treatment Group
Prior CDK inhibitor treatment duration >12 Months
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**71**	**43**	**33**	**19**	**15**	**10**	**9**	**8**	**4**	**4**	**3**	**2**	**2**	**2**	**1**	**1**	**0**
TPC	**61**	**48**	**30**	**17**	**10**	**7**	**4**	**3**	**1**	**1**	**1**	**1**	**0**				

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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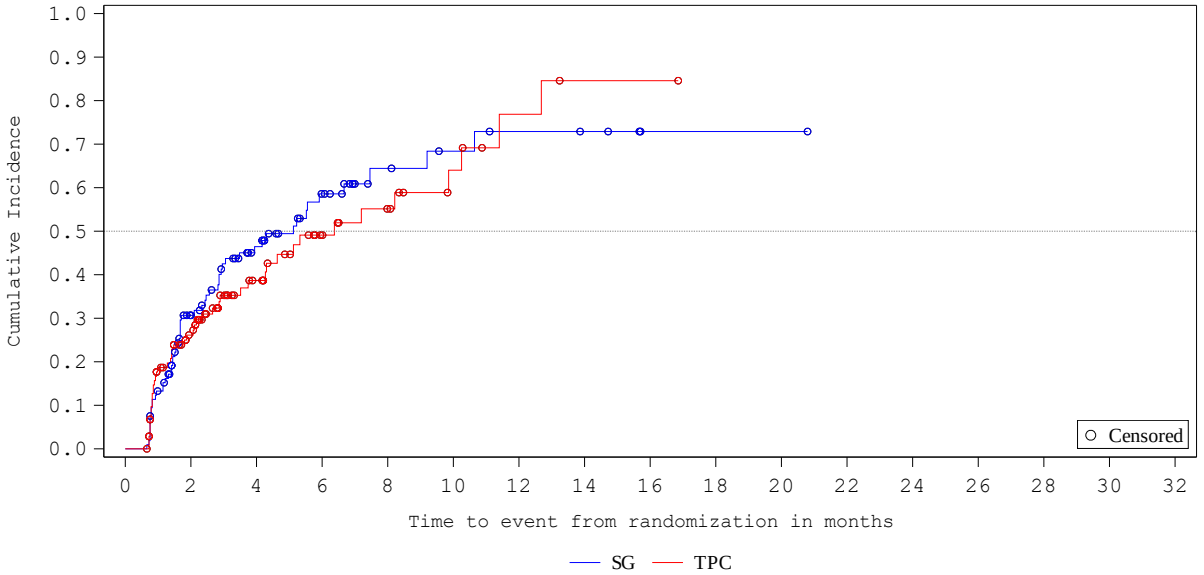
Figure 15.15.5.11.1.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Summary Score by Treatment Group
Geographic region = Europe
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	106	62	38	21	10	7	5	4	1	1	1	0
TPC	106	64	34	19	13	7	3	1	1	0		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Source: ADSL ADQS TPCCHOICE Program Name: f_surv_subgrp.sas Date Generated: 10MAY2023 Page 29 of 32

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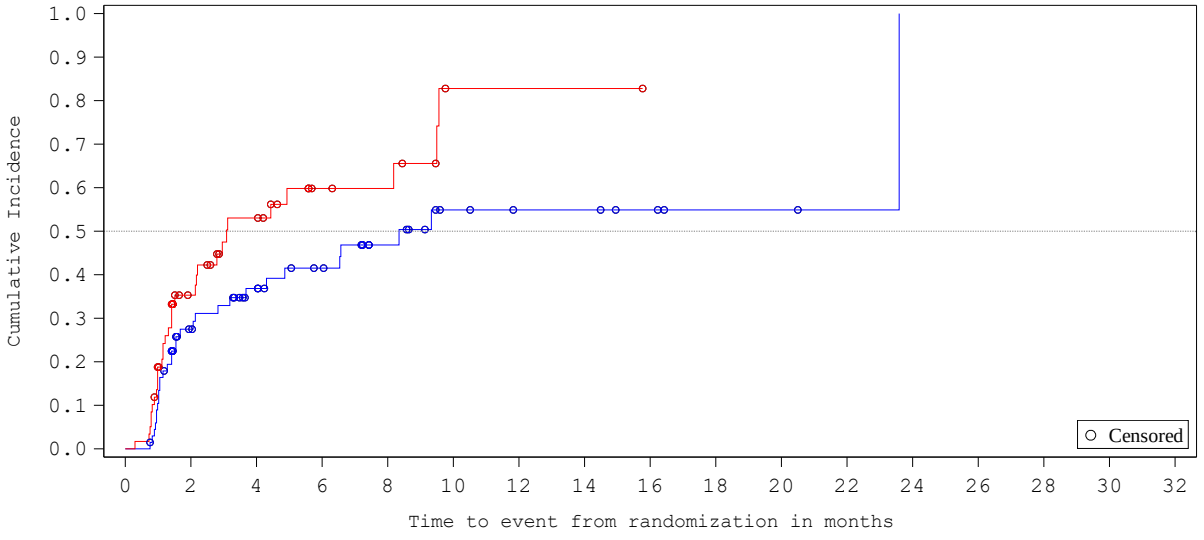
Figure 15.15.5.11.1.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Summary Score by Treatment Group
Geographic region = North America
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**68**	**41**	**30**	**23**	**15**	**8**	**6**	**6**	**4**	**2**	**2**	**1**	**0**
TPC	**59**	**28**	**17**	**8**	**7**	**1**	**1**	**1**	**0**				

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Source: ADSL ADQS TPCCHOICE Program Name: f_surv_subgrp.sas Date Generated: 10MAY2023 Page 30 of 32

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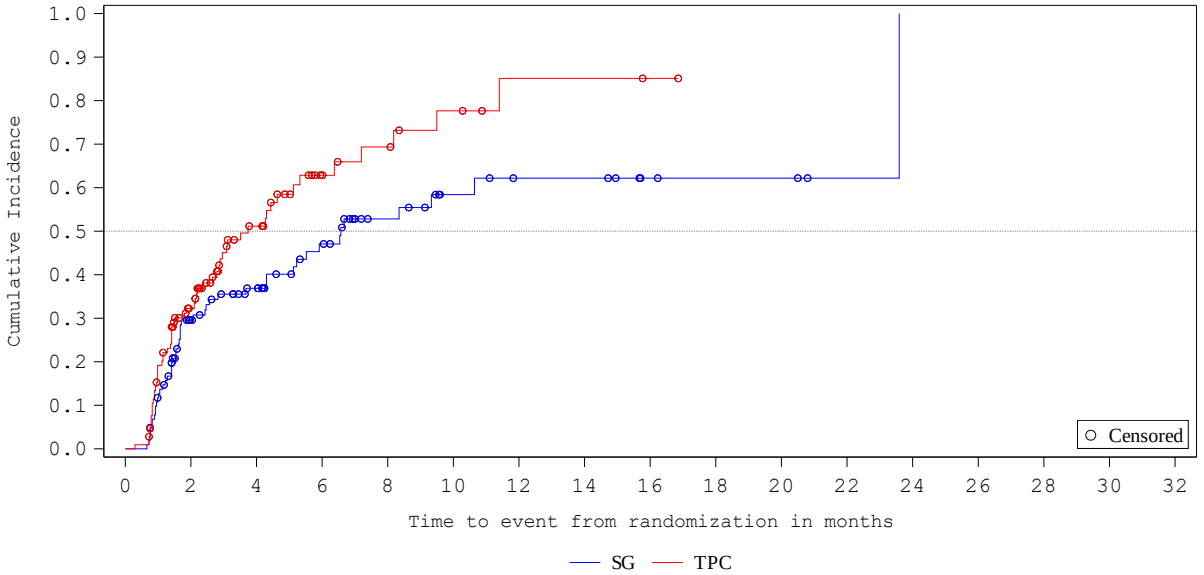
Figure 15.15.5.11.2.1
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Summary Score by Treatment Group
Chemotherapy in neo/adjuvant setting = Yes
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	103	61	46	30	18	11	8	8	4	3	3	1	0
TPC	107	60	30	13	9	5	2	2	1	0			

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

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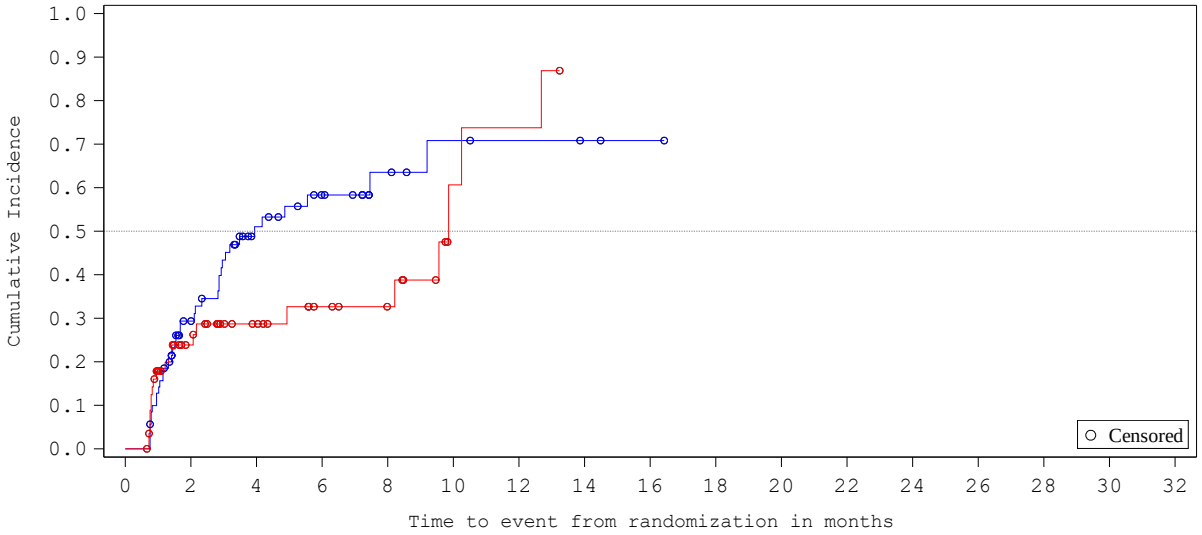
Figure 15.15.5.11.2.2
Kaplan-Meier Plot of Time to First Worsening with Death Being Censored for EORTC QLQ-C30 Summary Score by Treatment Group
Chemotherapy in neo/adjuvant setting = No
Excluding Subjects for Whom Gemcitabine was selected as TPC Prior to Randomization
Subjects with very poor baseline scores were excluded



Number at Risk (Events)

SG	**71**	**42**	**22**	**14**	**7**	**4**	**3**	**2**	**1**	**0**
TPC	**58**	**32**	**21**	**14**	**11**	**3**	**2**	**0**		

Note: "EORTC QLQ-C30 Evaluable population" is defined as ITT subjects who completed at least one of the 15 domains/scales at baseline and at least one evaluable assessment at post-baseline visits based on EORTC QLQ-C30. A clinically meaningful deterioration is defined as at least 10 points of worsening from baseline. Death is censored at the time of the last non-missing HRQoL assessment prior to death in the analysis. CI = Confidence Interval; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality-of-Life Core 30 questionnaire; HR = Hazard Ratio; QoL = Quality of Life; SG = Sacituzumab Govitecan; TPC = Treatment Physician Choice.

Source: ADSL ADQS TPCCHOICE Program Name: f_surv_subgrp.sas Date Generated: 10MAY2023 Page 32 of 32

Anhang 4-G 7: Unerwünschte Ereignisse

Anhang 4-G 7.1: Gesamtraten

Gilead Sciences, Inc.
Study IMMU-132-09

Table 15.11.2.1.1: Time to the First Treatment-Emergent Adverse Event (TEAE)
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	201 (100.0%)	185 (95.4%)	
Patients Without Events (Censored) (%)	0	9 (4.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.530 (1.243, 1.883)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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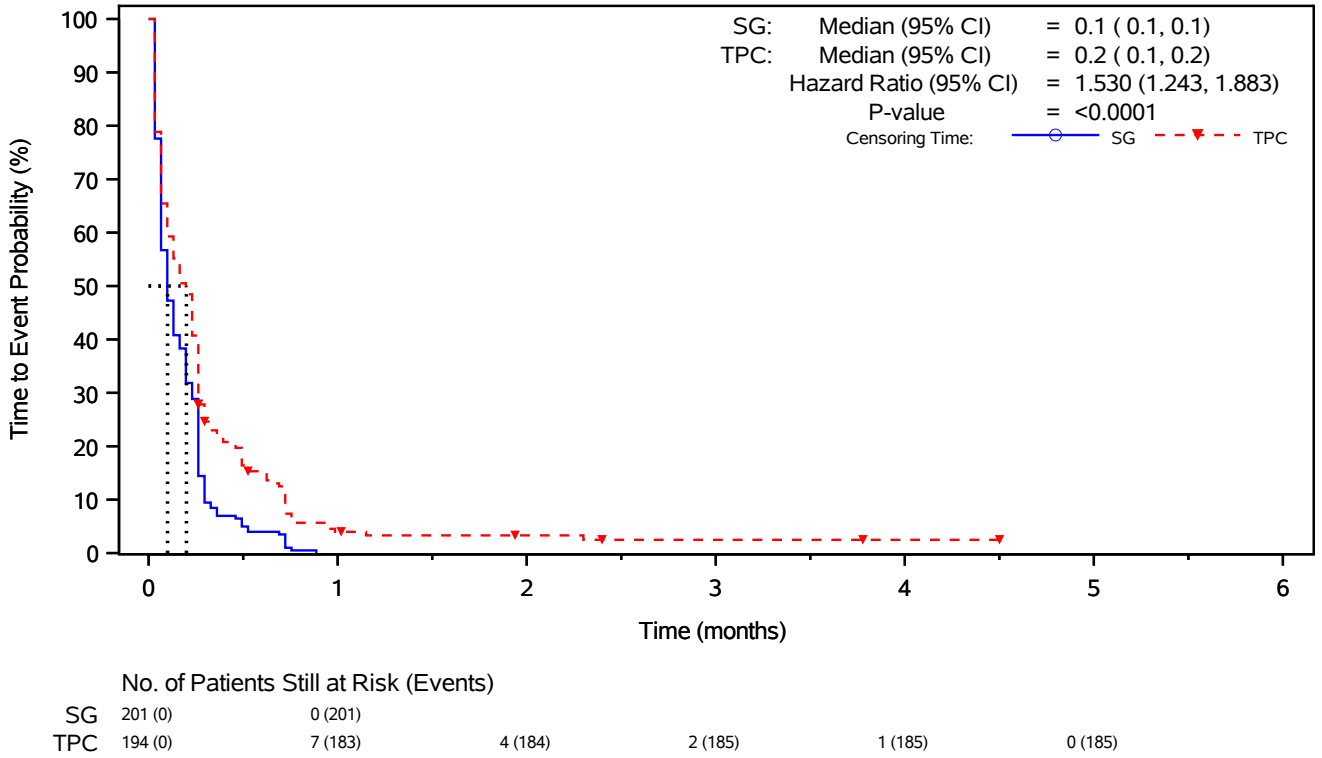
Gilead Sciences, Inc.
Study IMMU-132-09

Figure 15.11.2.1.1: KM Plot for Time to the First TEAE
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Gilead Sciences, Inc.
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Table 15.11.2.2.1: Time to the First Serious Treatment-Emergent Adverse Event (SAE)
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	55 (27.4%)	34 (17.5%)	
Patients Without Events (Censored) (%)	146 (72.6%)	160 (82.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.424 (0.925, 2.193)
p-value			0.1068

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.
The analysis is based on Interim 2 data cut at 7/1/2022.

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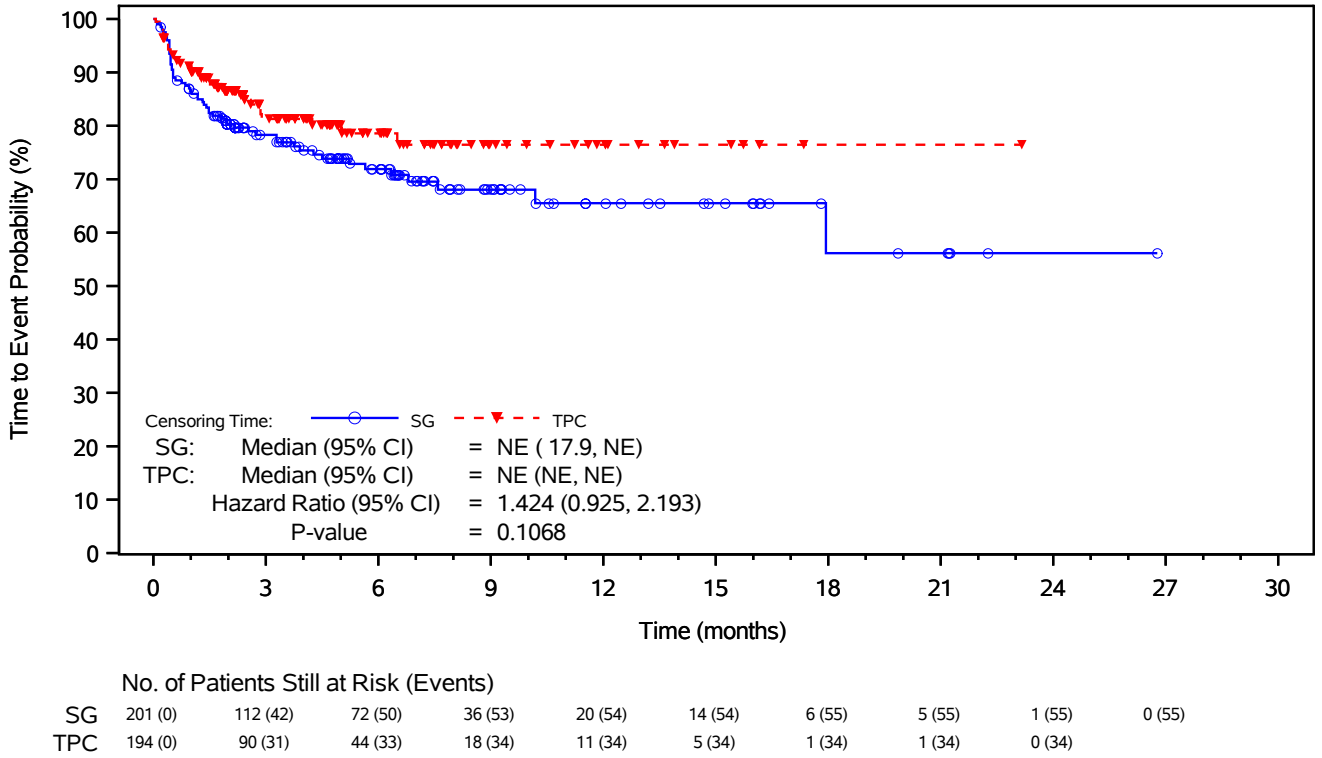
Figure 15.11.2.2.1: KM Plot for Time to the First Serious TEAE
Safety Population
Excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	201 (0)	112 (42)	72 (50)	36 (53)	20 (54)	14 (54)	6 (55)	5 (55)	1 (55)	0 (55)
TPC	194 (0)	90 (31)	44 (33)	18 (34)	11 (34)	5 (34)	1 (34)	1 (34)	0 (34)	

The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.11.2.3.1: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE)
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	151 (75.1%)	110 (56.7%)	
Patients Without Events (Censored) (%)	50 (24.9%)	84 (43.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.7, 1.0)	2.4 (1.1, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.493 (1.165, 1.912)
p-value			0.0015

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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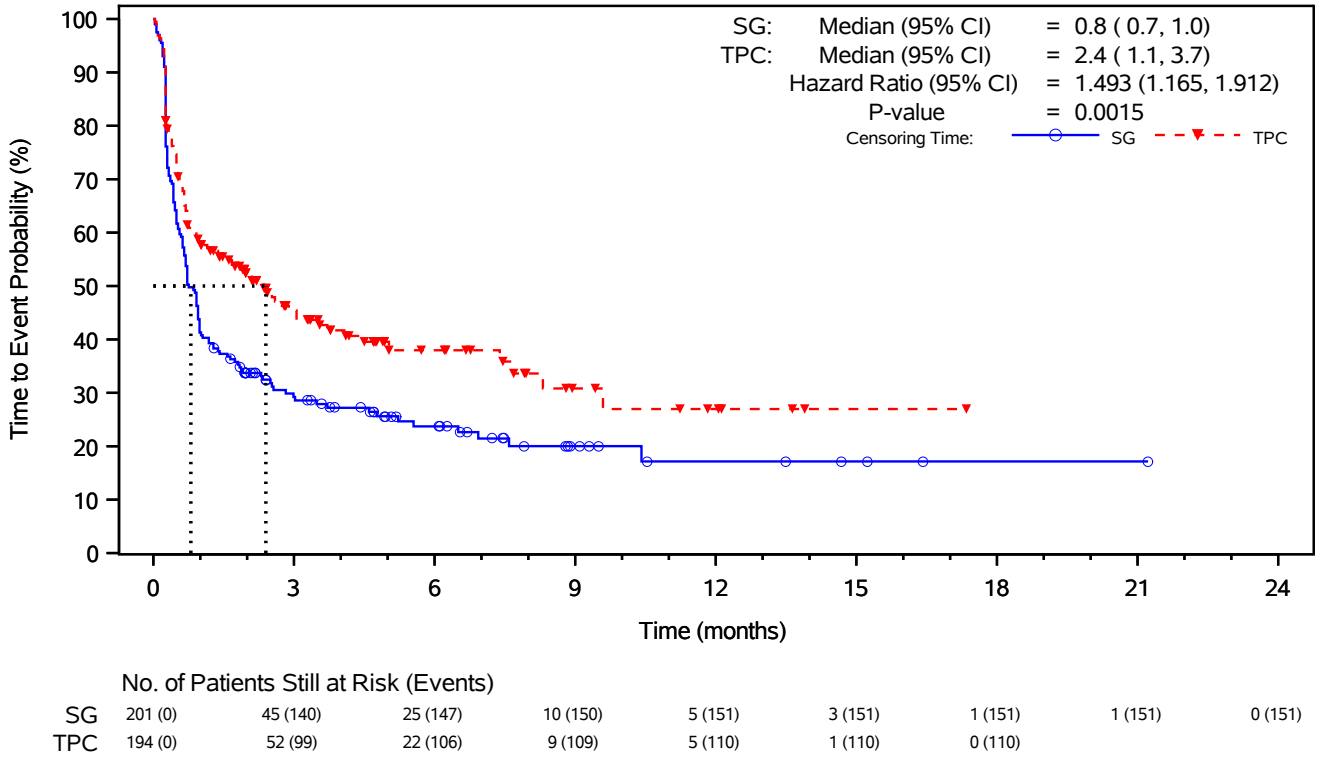
Gilead Sciences, Inc.
Study IMMU-132-09

Figure 15.11.2.3.1: KM Plot for Time to the First Grade 3 or Higher TEAE
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.11.5.1: Time to the First TEAE Leading to Any Study Drug Discontinuation
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	14 (7.0%)	6 (3.1%)	
Patients Without Events (Censored) (%)	187 (93.0%)	188 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.701 (0.639, 4.527)
p-value			0.2816

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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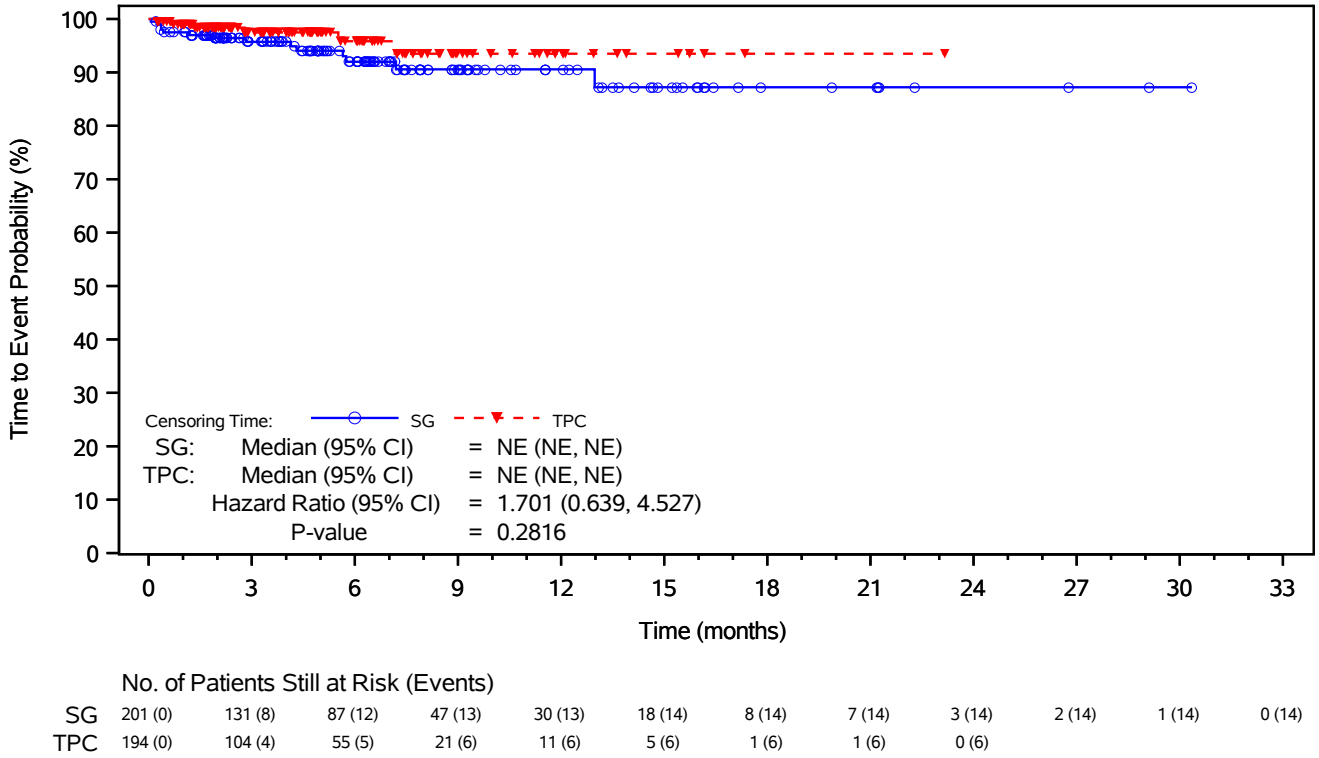
Gilead Sciences, Inc.
Study IMMU-132-09

Figure 15.11.5.1: KM Plot for Time to the First TEAE Leading to Any Study Drug Discontinuation
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.11.3.1: Time to the First Treatment-Emergent Adverse Event (TEAE) Leading to Death
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	4 (2.0%)	0	
Patients Without Events (Censored) (%)	197 (98.0%)	194 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0925

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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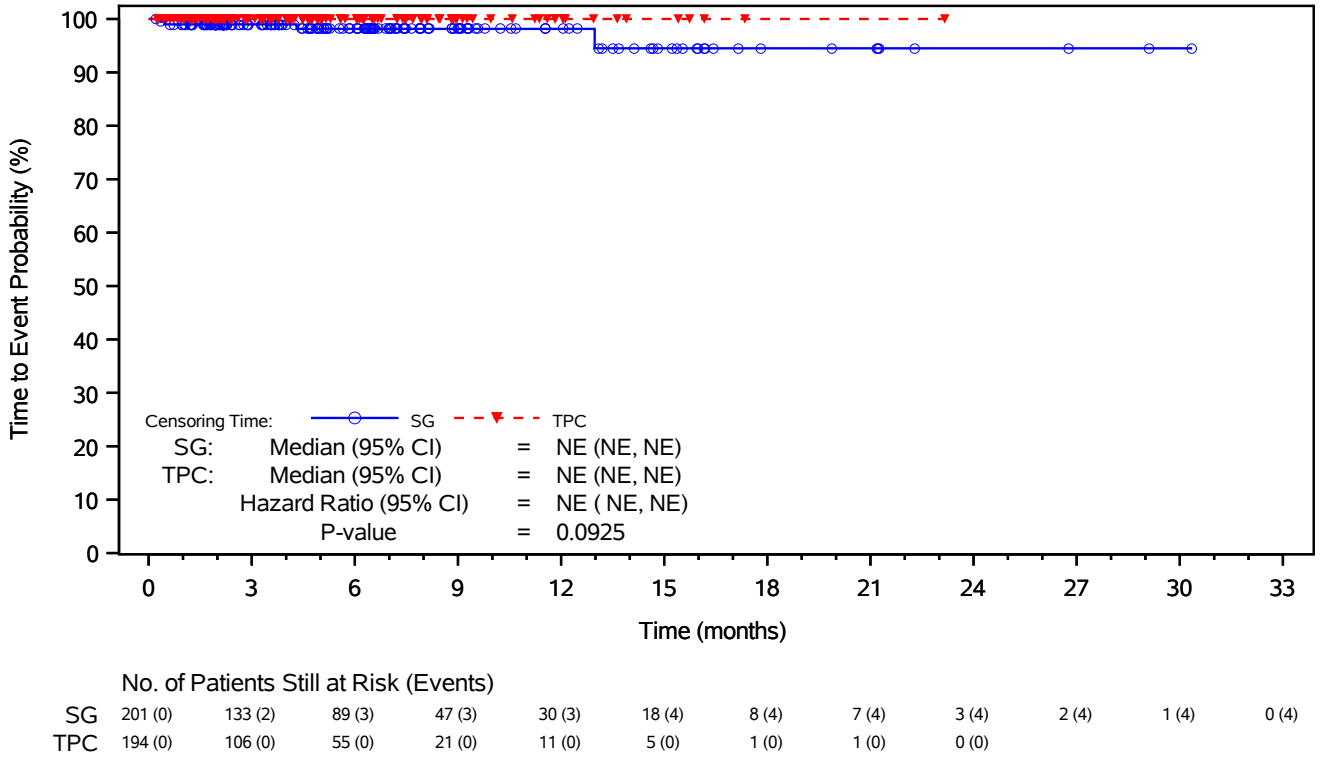
Figure 15.11.3.1: KM Plot for Time to the First TEAE Leading to Death
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Anhang 4-G 7.2: Gesamtraten unter Ausschluss erkrankungsbezogener Ereignisse

Gilead Sciences, Inc.
Study IMMU-132-09

Table 15.11.6.1: Time to the First TEAE Excluding Disease-Related Events
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	201 (100.0%)	185 (95.4%)	
Patients Without Events (Censored) (%)	0	9 (4.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.530 (1.243, 1.883)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Disease-related events are Cancer pain, Tumour pain, Malignant pleural effusion and Metastases to skin in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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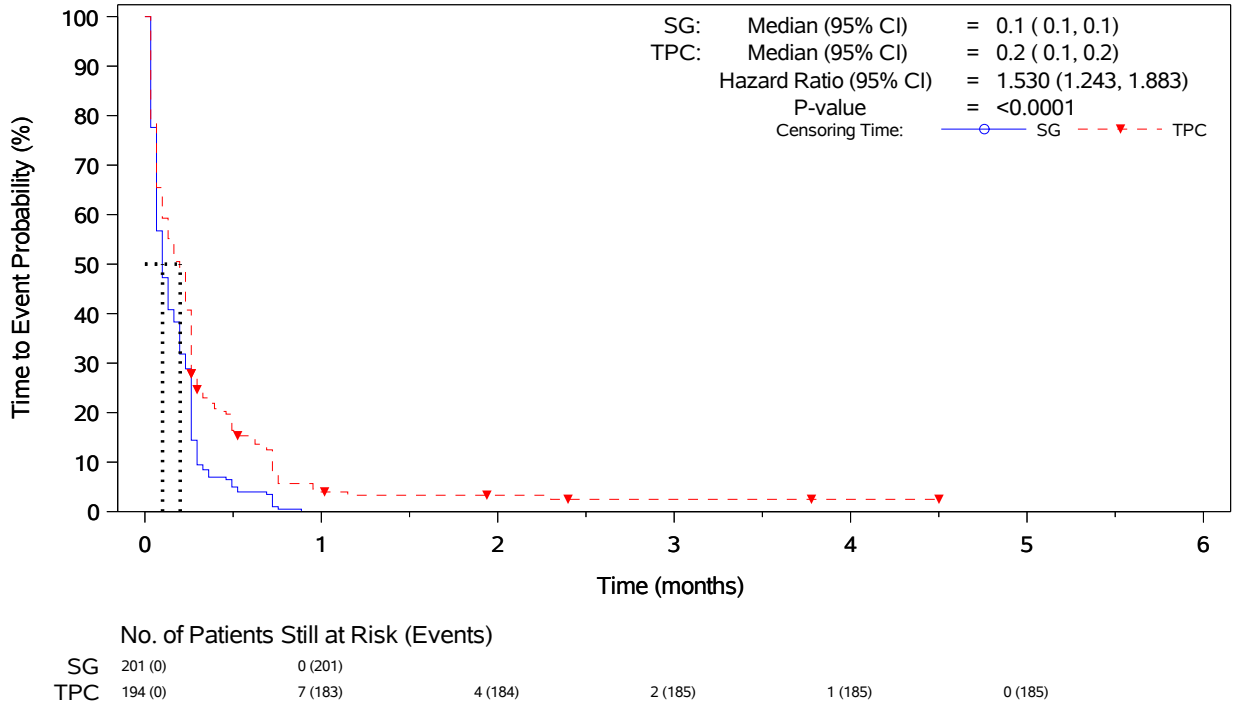
Figure 15.11.6.1: KM Plot for Time to the First TEAE Excluding Disease-Related Events
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Disease-related events are Cancer pain, Tumour pain, Malignant pleural effusion and Metastases to skin in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.11.6.2: Time to the First Serious TEAE Excluding Disease-Related Events
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	55 (27.4%)	34 (17.5%)	
Patients Without Events (Censored) (%)	146 (72.6%)	160 (82.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.424 (0.925, 2.193)
p-value			0.1068

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Disease-related events are Cancer pain, Tumour pain, Malignant pleural effusion and Metastases to skin in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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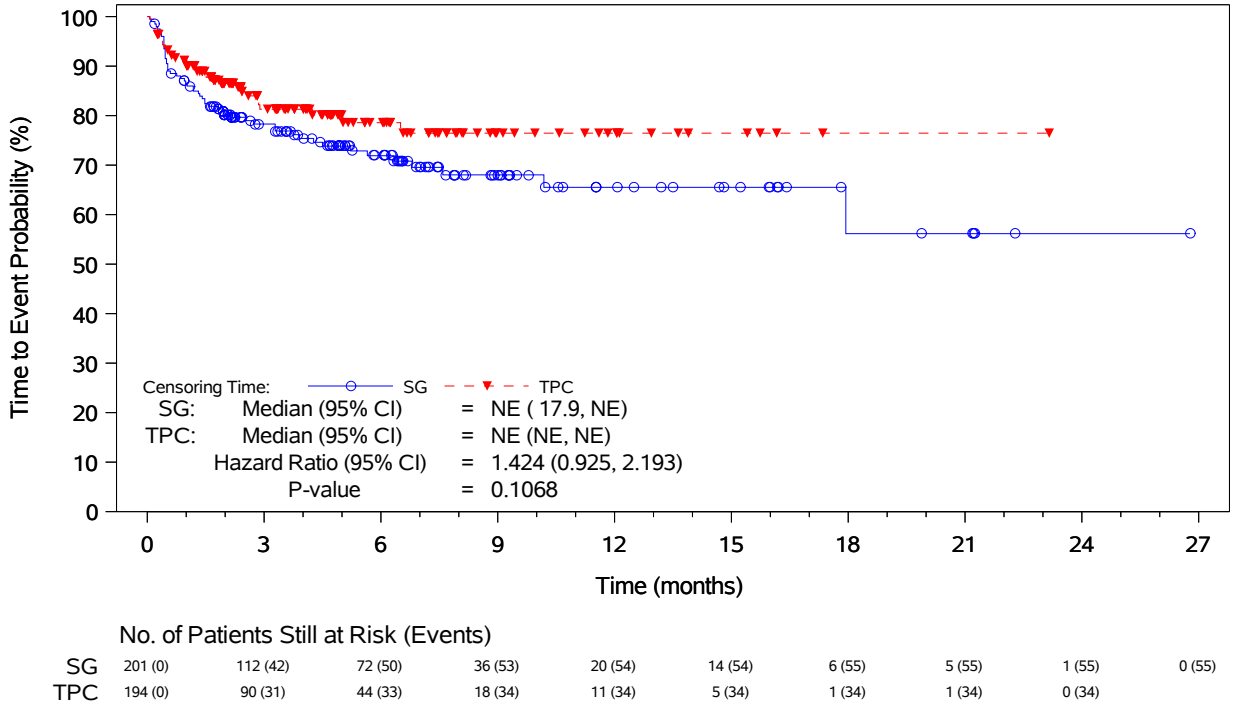
Figure 15.11.6.2: KM Plot for Time to the First Serious TEAE Excluding Disease-Related Events
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Disease-related events are Cancer pain, Tumour pain, Malignant pleural effusion and Metastases to skin in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.11.6.3: Time to the First Grade 3 or Higher TEAE Excluding Disease-Related Events
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients With Events (%)	151 (75.1%)	110 (56.7%)	
Patients Without Events (Censored) (%)	50 (24.9%)	84 (43.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.7, 1.0)	2.4 (1.1, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.493 (1.165, 1.912)
p-value			0.0015

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Disease-related events are Cancer pain, Tumour pain, Malignant pleural effusion and Metastases to skin in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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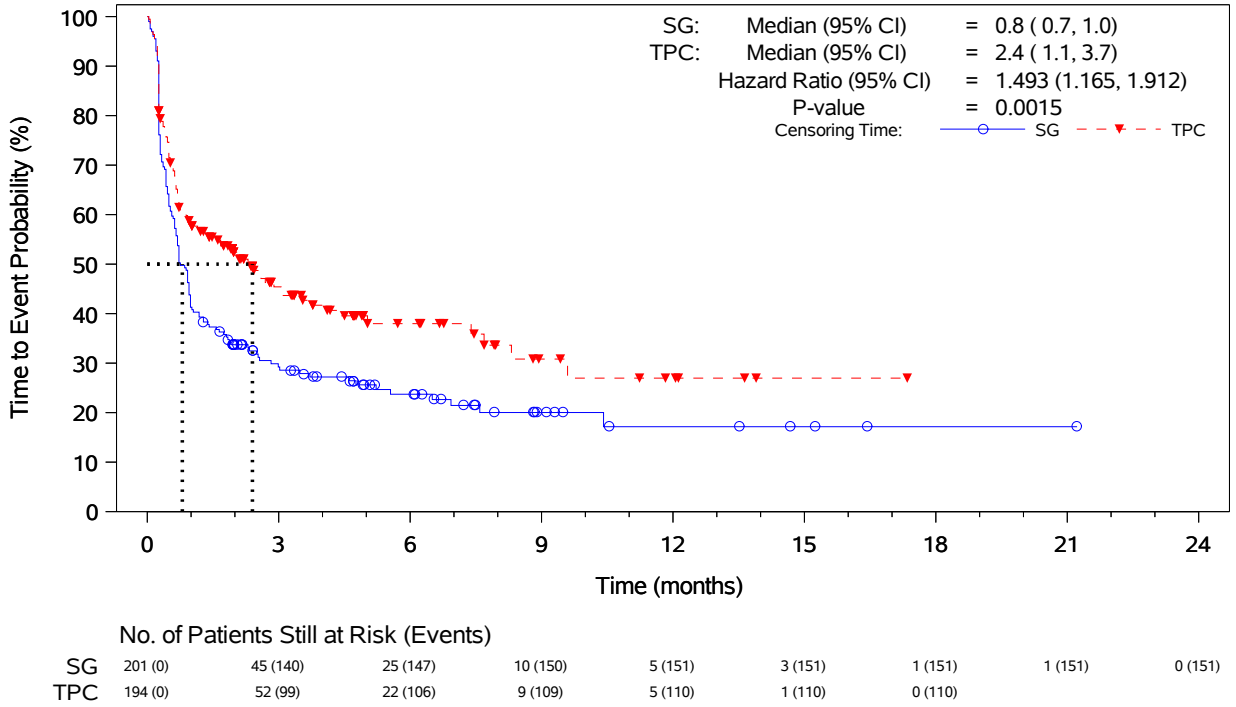
Figure 15.11.6.3: KM Plot for Time to the First Grade 3 or Higher TEAE Excluding Disease-Related Events
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Disease-related events are Cancer pain, Tumour pain, Malignant pleural effusion and Metastases to skin in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Anhang 4-G 7.3: UE von besonderem Interesse

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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Patients With Events (%)	187 (93.0%)	157 (80.9%)	
Patients Without Events (Censored) (%)	14 (7.0%)	37 (19.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.6 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.572 (1.267, 1.952)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Patients With Events (%)	120 (59.7%)	49 (25.3%)	
Patients Without Events (Censored) (%)	81 (40.3%)	145 (74.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.3, 3.3)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.077 (2.196, 4.311)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Patients With Events (%)	12 (6.0%)	11 (5.7%)	
Patients Without Events (Censored) (%)	189 (94.0%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.054 (0.464, 2.393)
p-value			0.9016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Patients With Events (%)	56 (27.9%)	35 (18.0%)	
Patients Without Events (Censored) (%)	145 (72.1%)	159 (82.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (28.1, NE)	NE (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.531 (0.995, 2.356)
p-value			0.0503

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Patients With Events (%)	76 (37.8%)	55 (28.4%)	
Patients Without Events (Censored) (%)	125 (62.2%)	139 (71.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (6.4, 15.8)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.139 (0.802, 1.619)
p-value			0.4680

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Patients With Events (%)	35 (17.4%)	54 (27.8%)	
Patients Without Events (Censored) (%)	166 (82.6%)	140 (72.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (6.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.453 (0.293, 0.700)
p-value			0.0003

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Patients With Events (%)	147 (73.1%)	103 (53.1%)	
Patients Without Events (Censored) (%)	54 (26.9%)	91 (46.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.9)	2.5 (1.6, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.674 (1.296, 2.162)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
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Table 15.11.4.1: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Pulmonary events+			
Patients With Events (%)	0	1 (0.5%)	
Patients Without Events (Censored) (%)	201 (100.0%)	193 (99.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3083

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
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Figure 15.11.4.1: KM Plot for Time to the First TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

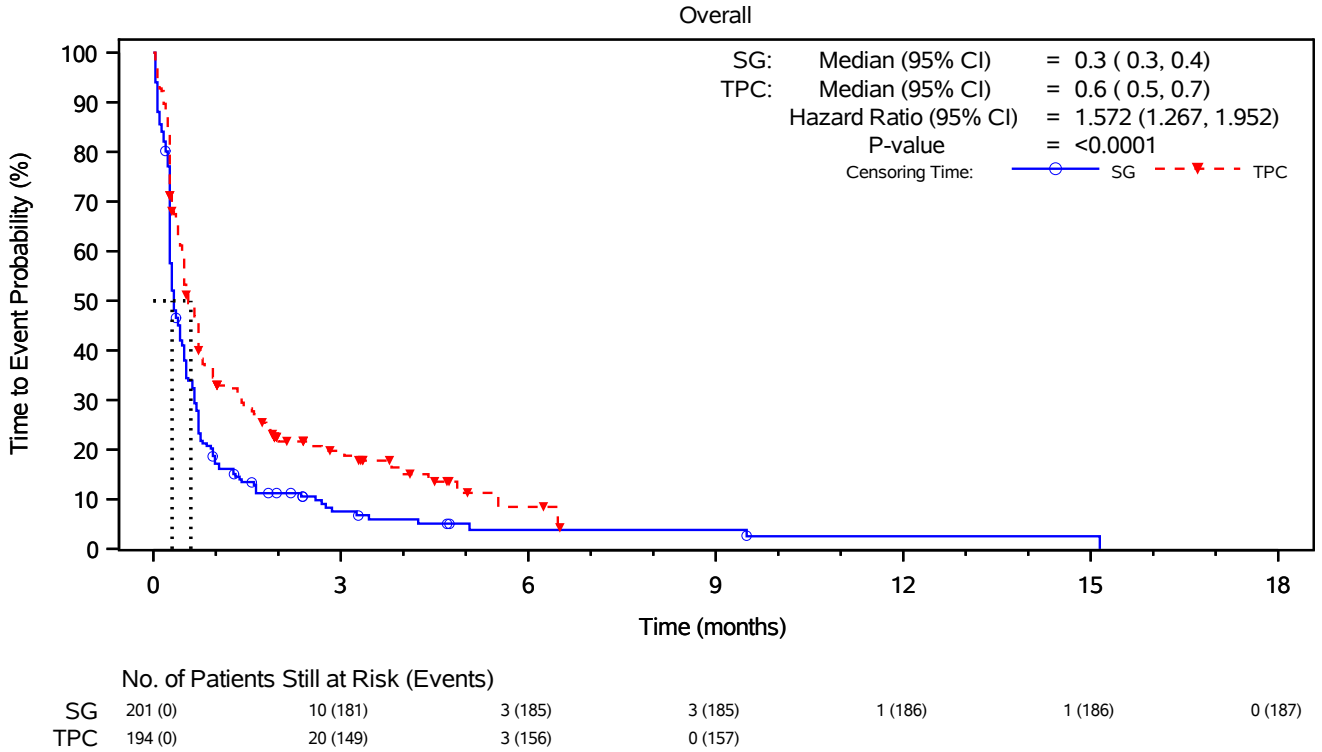

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Figure 15.11.4.1: KM Plot for Time to the First TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

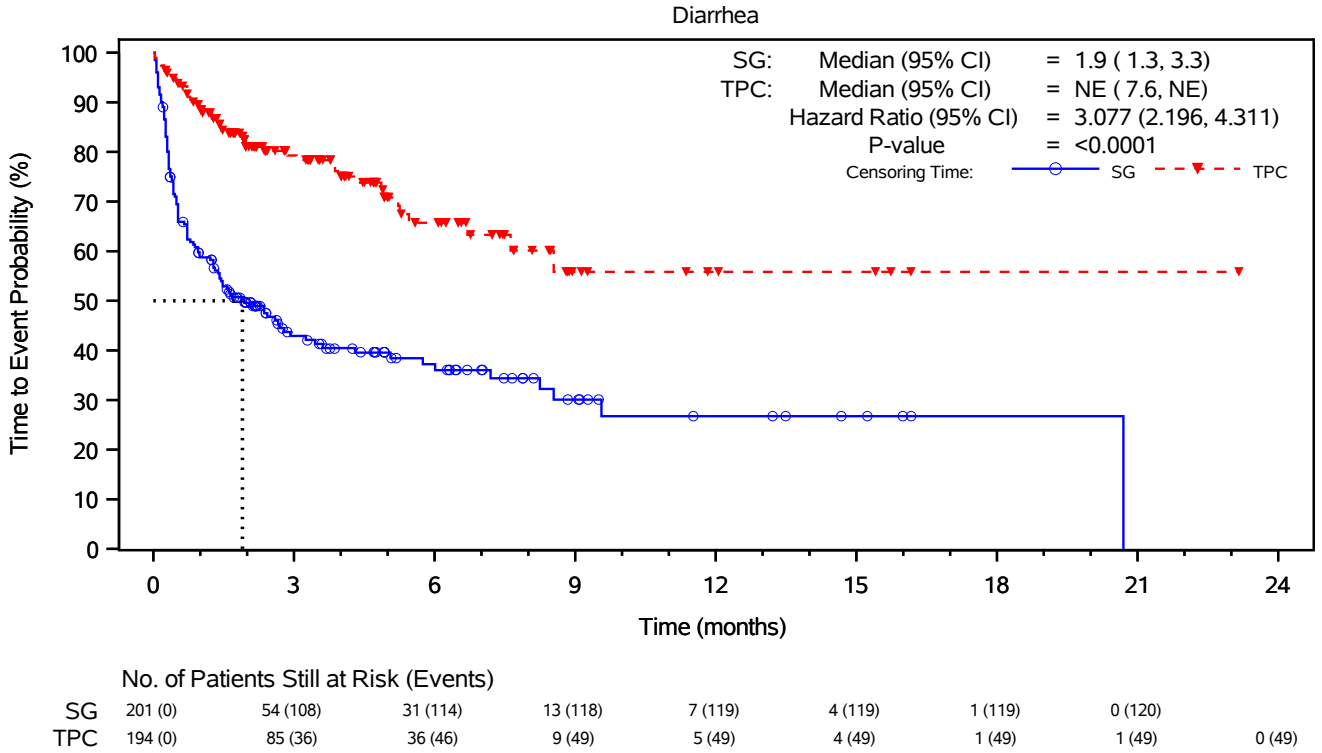

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Figure 15.11.4.1: KM Plot for Time to the First TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

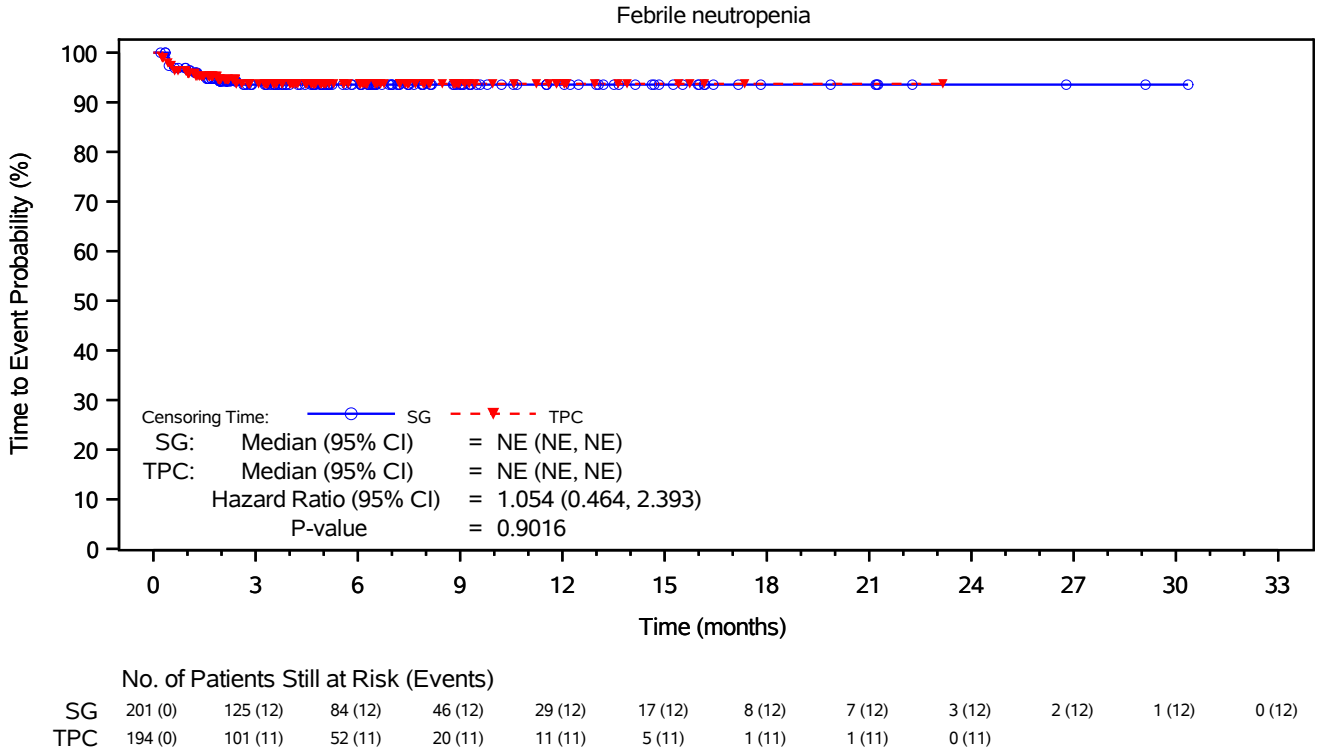

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Figure 15.11.4.1: KM Plot for Time to the First TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

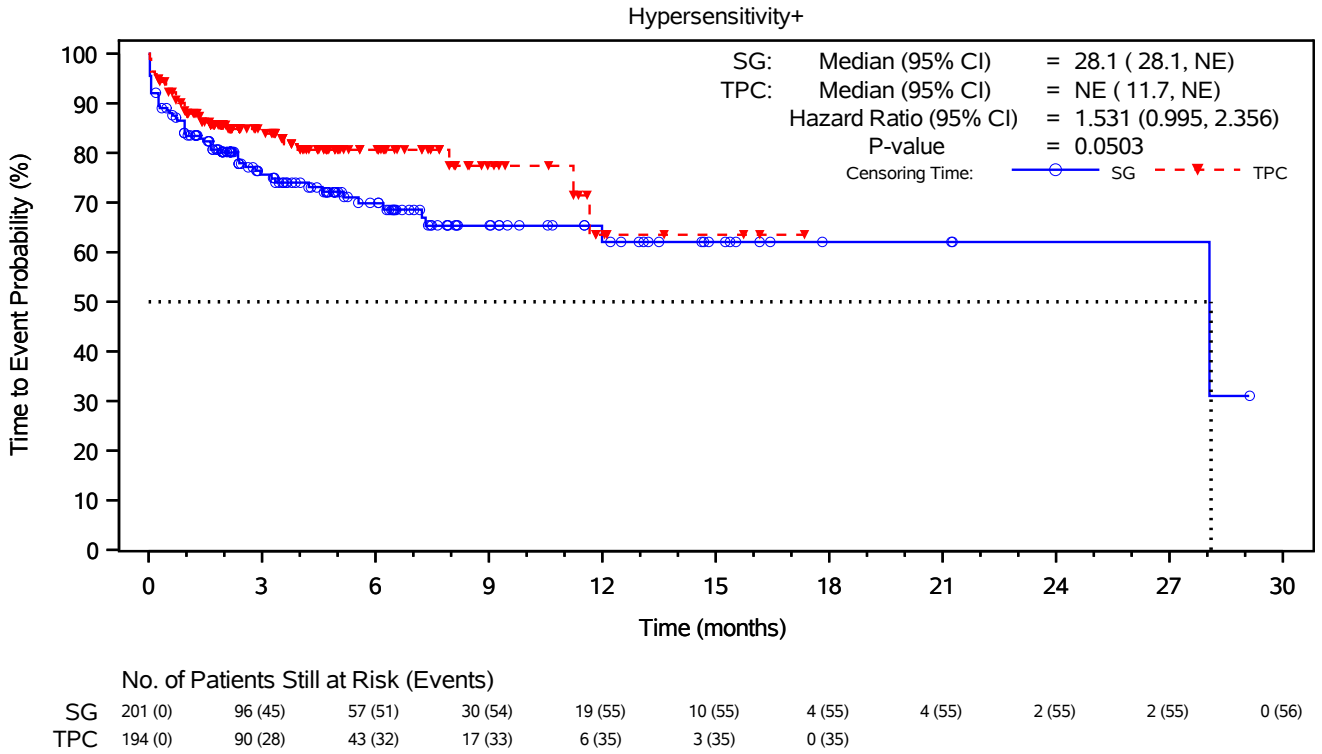

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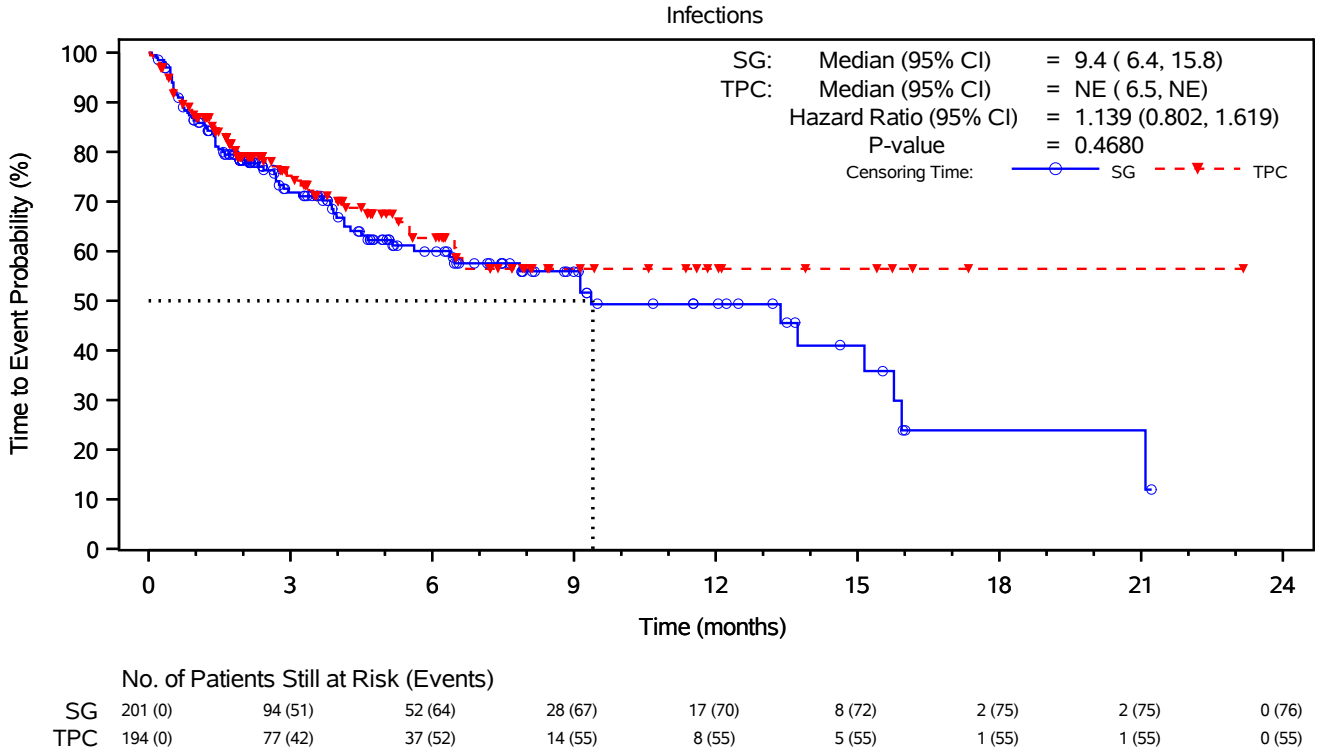
Figure 15.11.4.1: KM Plot for Time to the First TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



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Safety Population
Excluding participants pre-selected to Gemcitabine

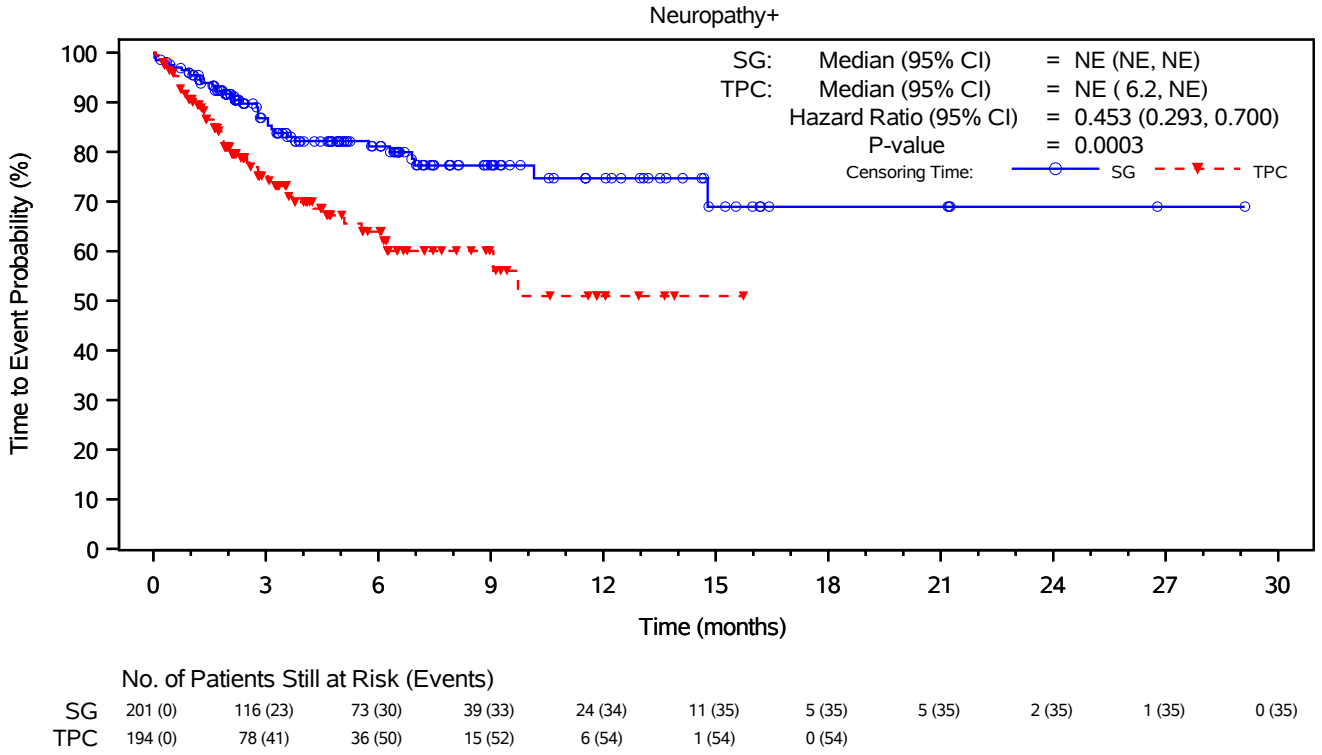

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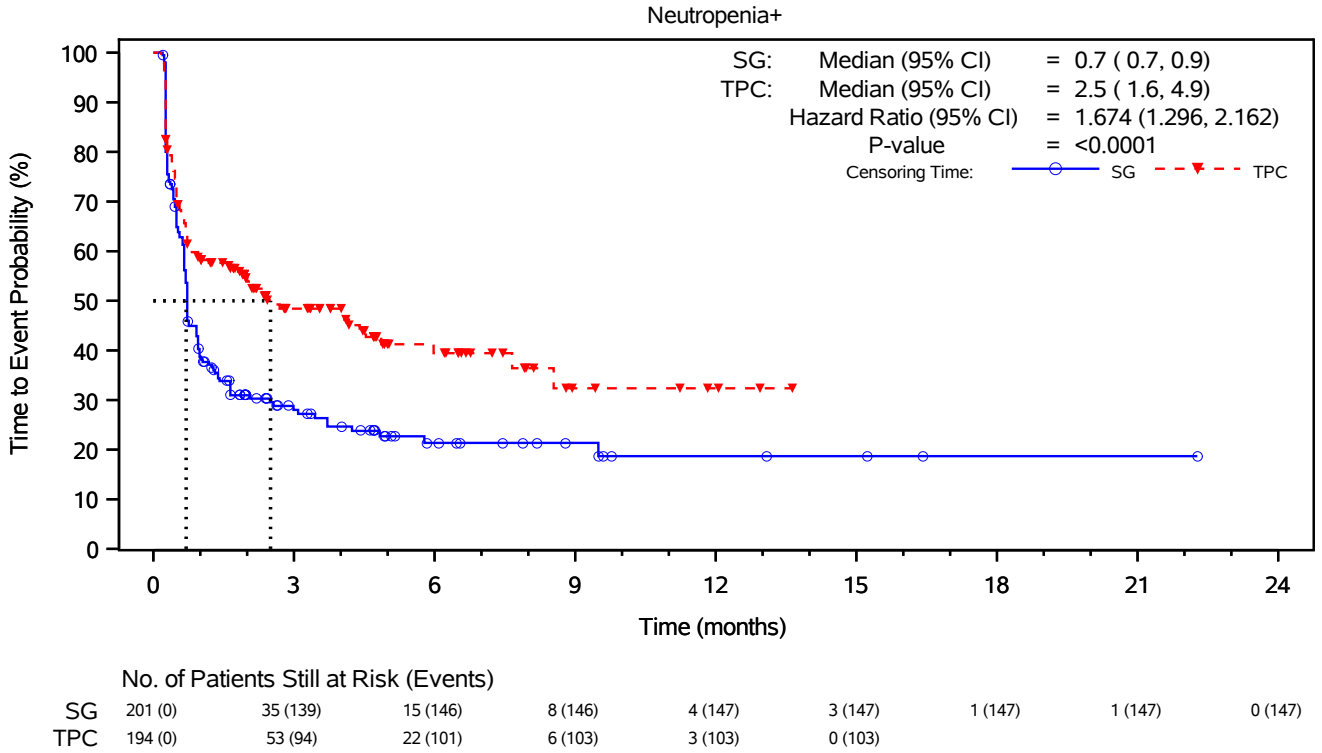
Figure 15.11.4.1: KM Plot for Time to the First TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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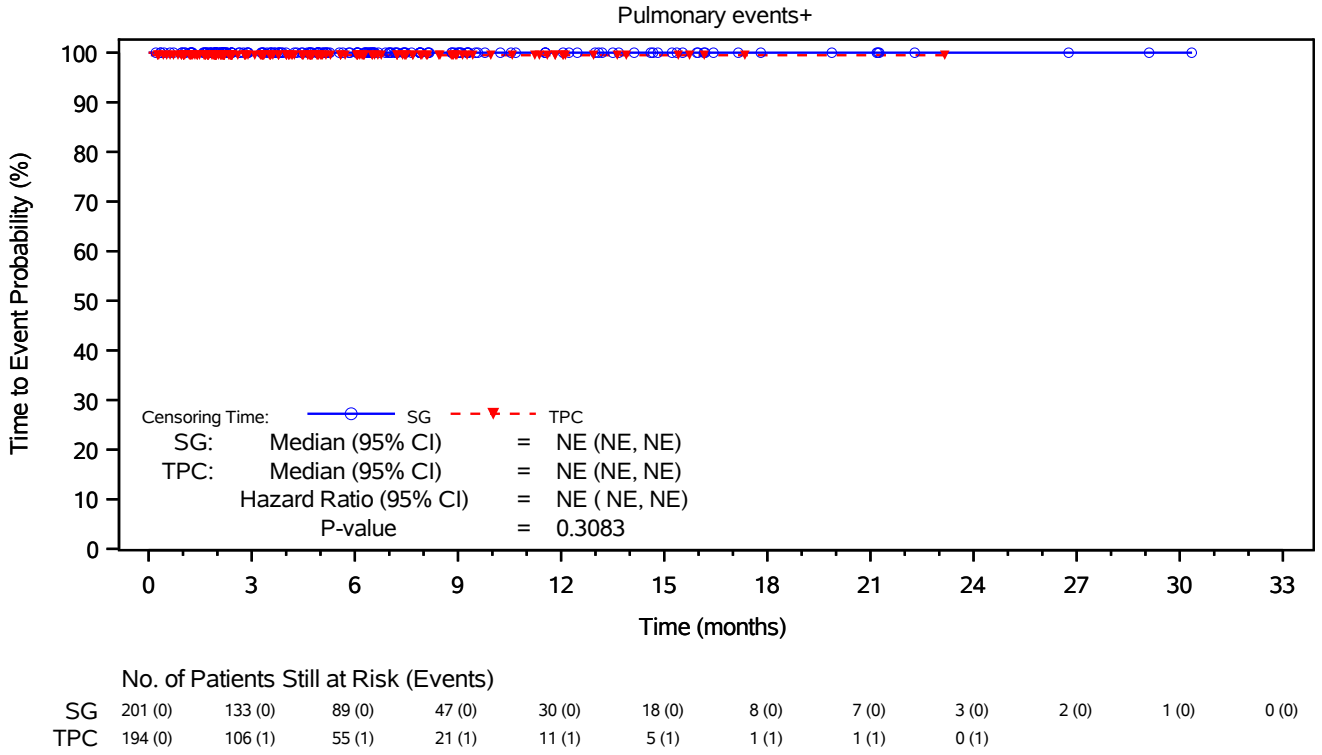
Figure 15.11.4.1: KM Plot for Time to the First TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Patients With Events (%)	35 (17.4%)	20 (10.3%)	
Patients Without Events (Censored) (%)	166 (82.6%)	174 (89.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.573 (0.903, 2.738)
p-value			0.1073

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Patients With Events (%)	9 (4.5%)	1 (0.5%)	
Patients Without Events (Censored) (%)	192 (95.5%)	193 (99.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			8.550 (1.083, 67.502)
p-value			0.0143

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Patients With Events (%)	8 (4.0%)	10 (5.2%)	
Patients Without Events (Censored) (%)	193 (96.0%)	184 (94.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.779 (0.307, 1.978)
p-value			0.5977

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Patients With Events (%)	0	0	
Patients Without Events (Censored) (%)	201 (100.0%)	194 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Patients With Events (%)	19 (9.5%)	8 (4.1%)	
Patients Without Events (Censored) (%)	182 (90.5%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.943 (0.840, 4.494)
p-value			0.1139

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Patients With Events (%)	1 (0.5%)	0	
Patients Without Events (Censored) (%)	200 (99.5%)	194 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3596

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Patients With Events (%)	14 (7.0%)	12 (6.2%)	
Patients Without Events (Censored) (%)	187 (93.0%)	182 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.120 (0.517, 2.423)
p-value			0.7746

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
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Table 15.11.4.3: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Pulmonary events+			
Patients With Events (%)	0	0	
Patients Without Events (Censored) (%)	201 (100.0%)	194 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

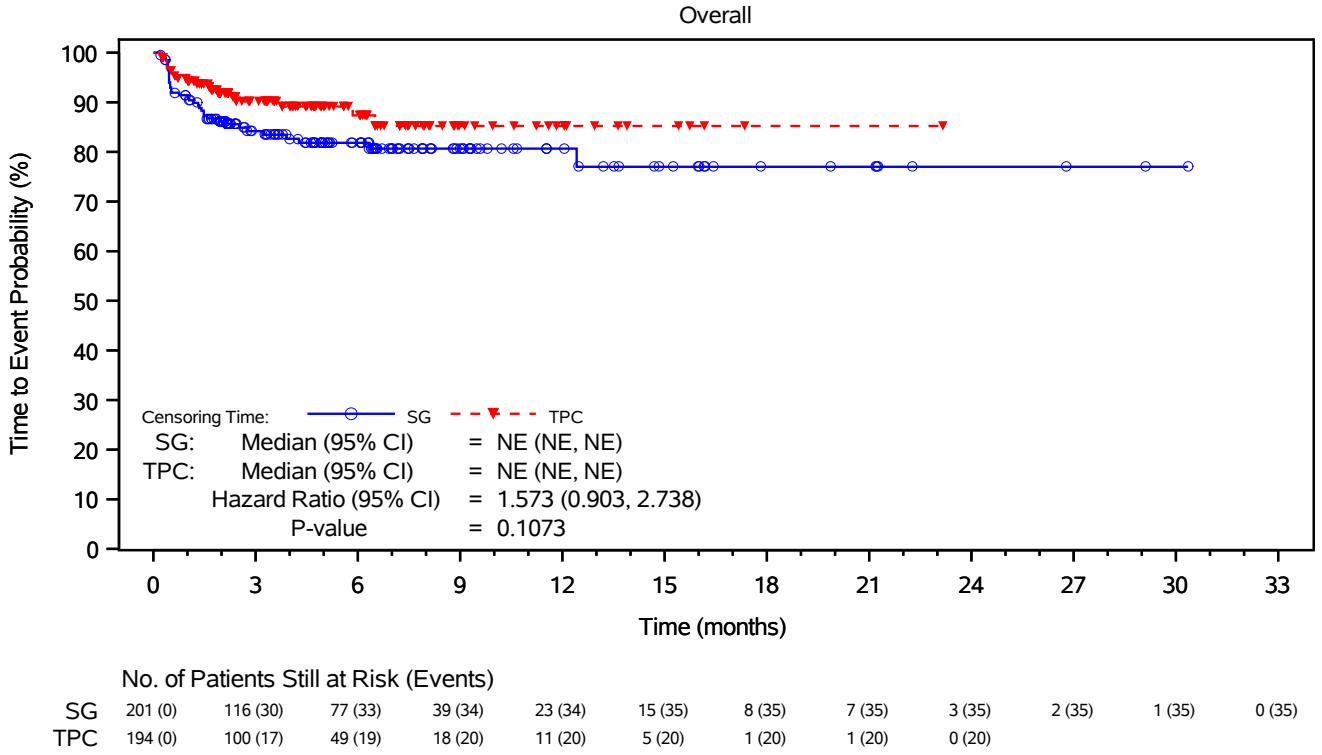

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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

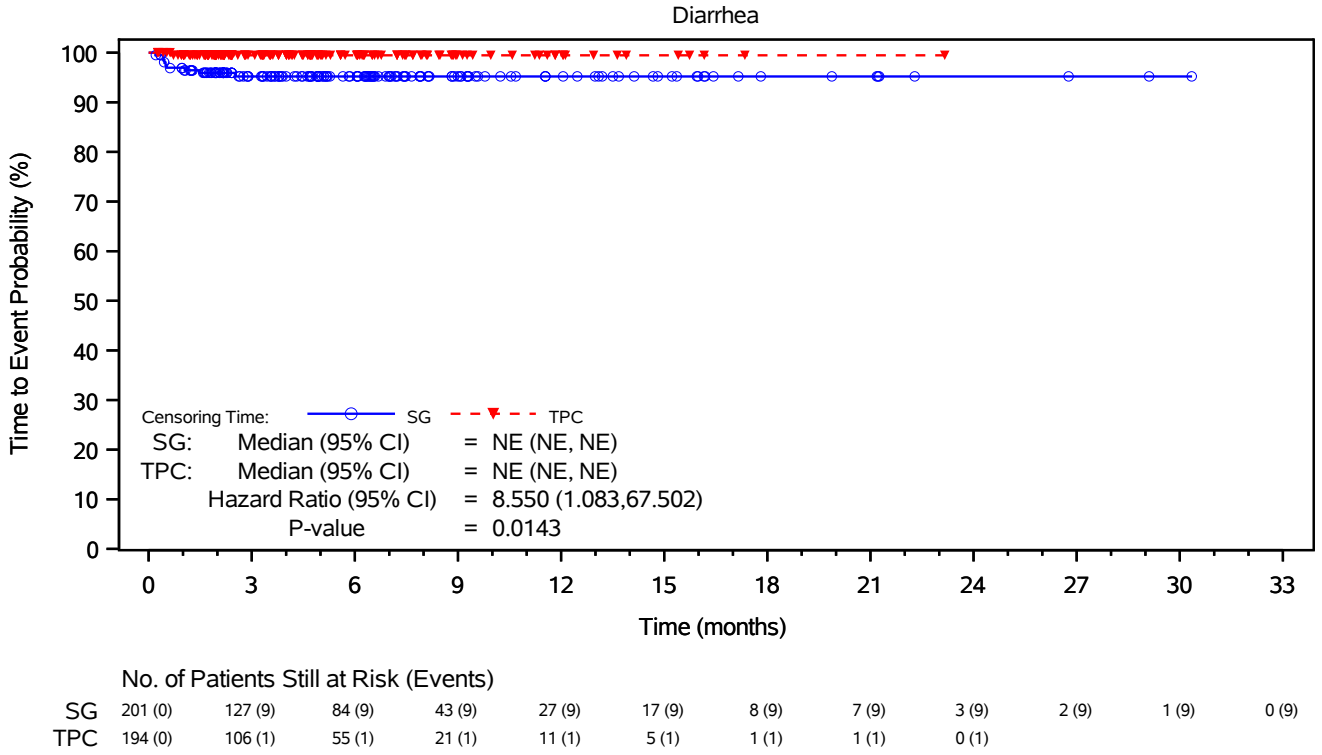

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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

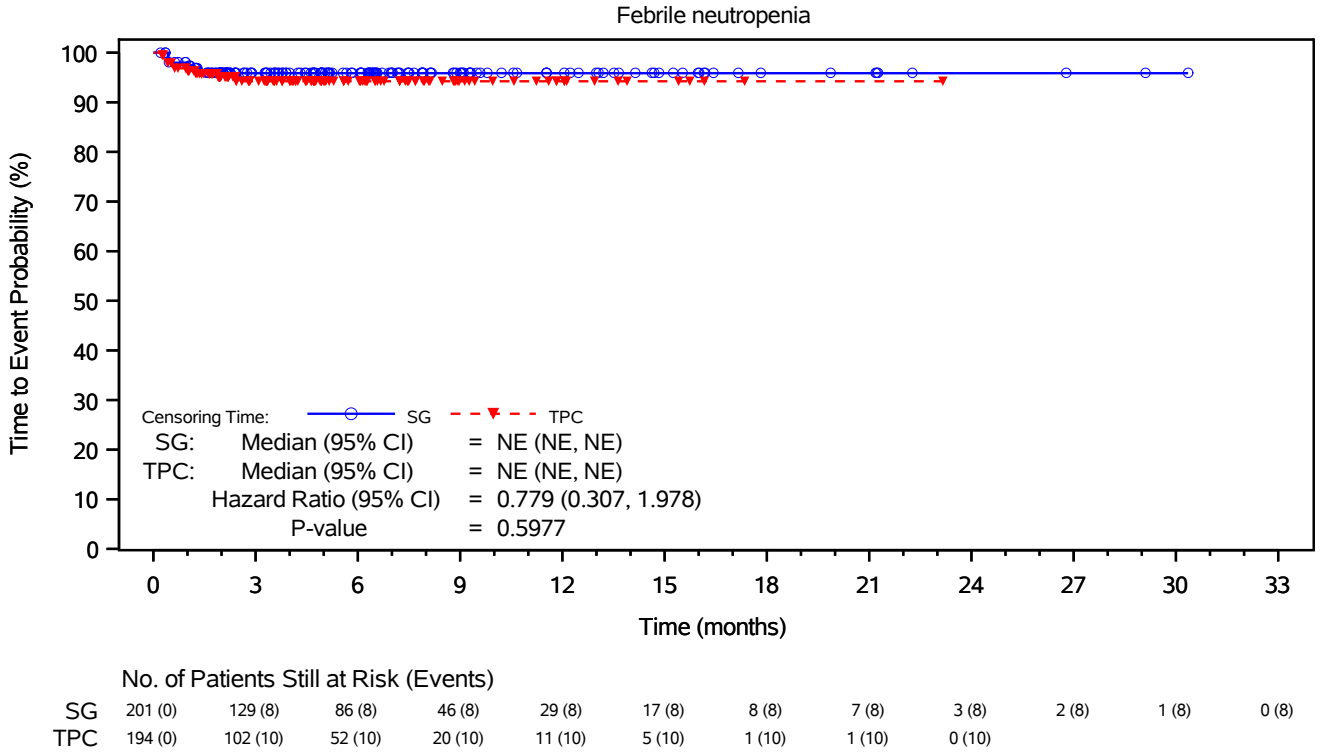

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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

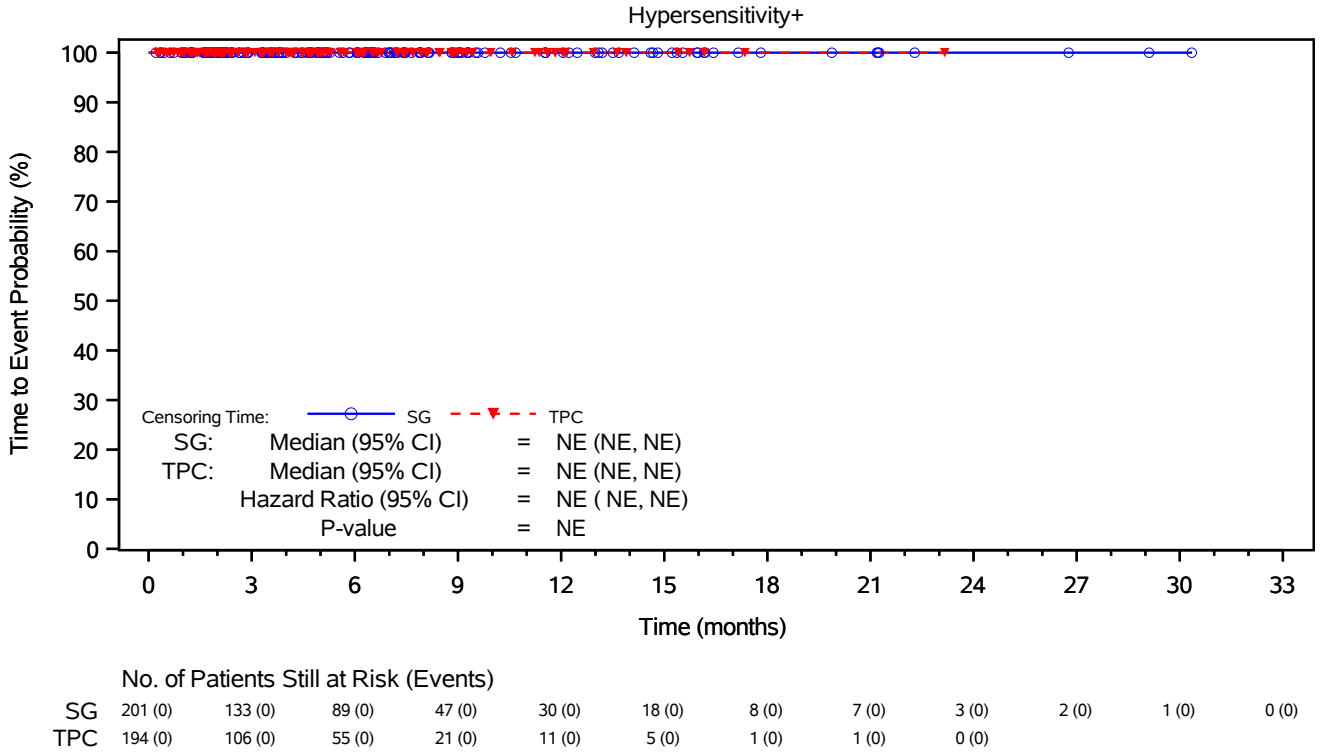

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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

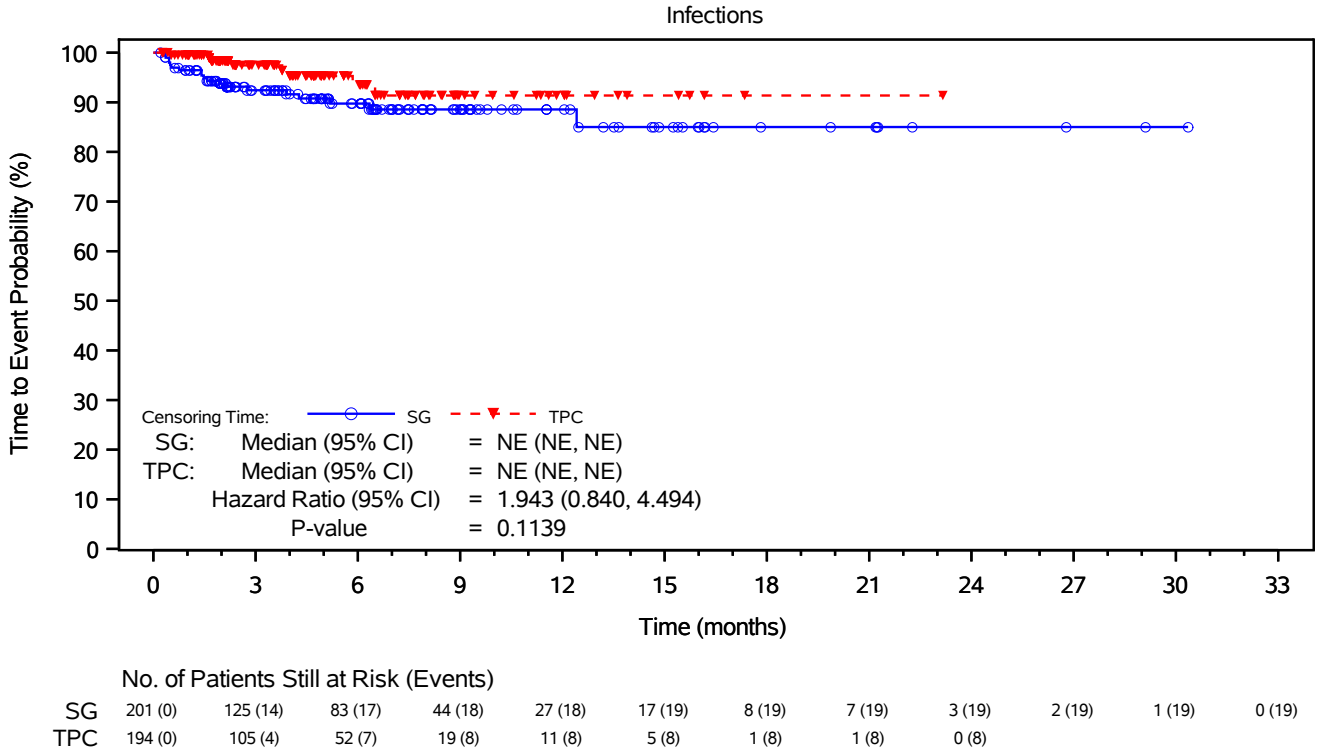

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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

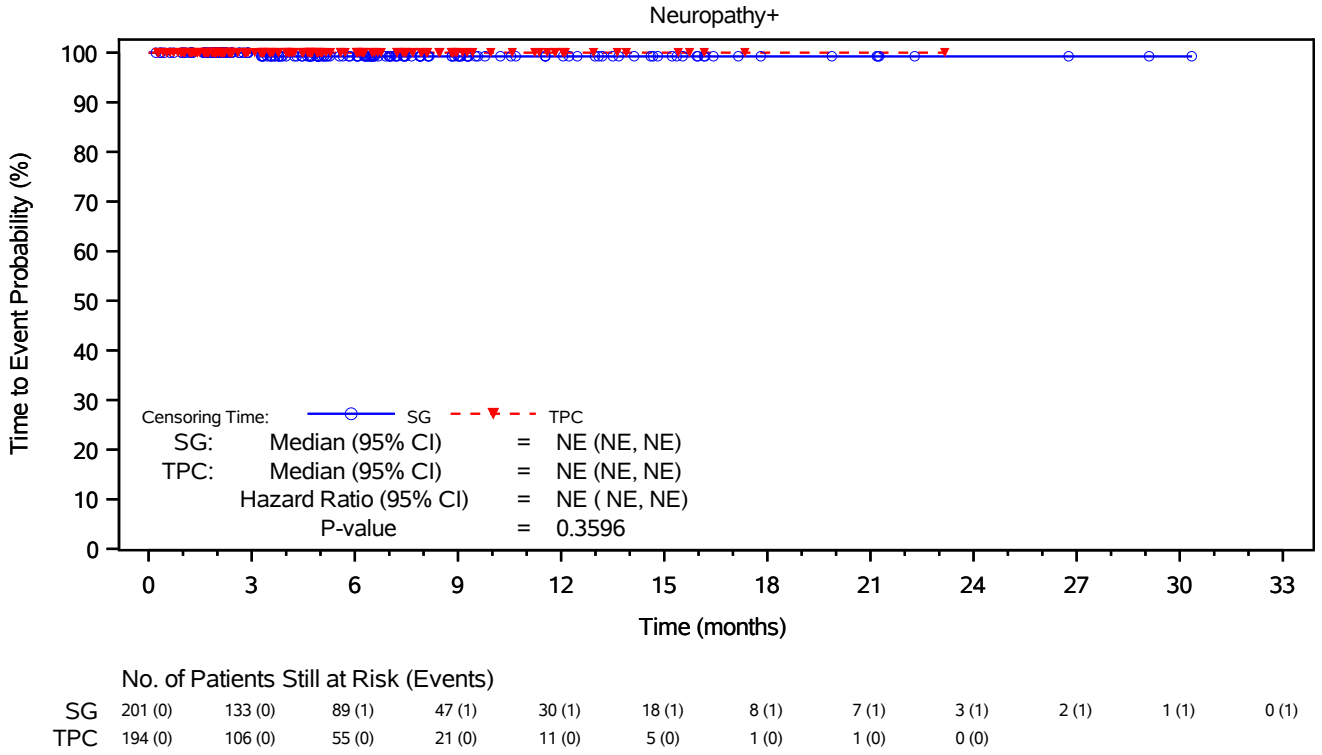

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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

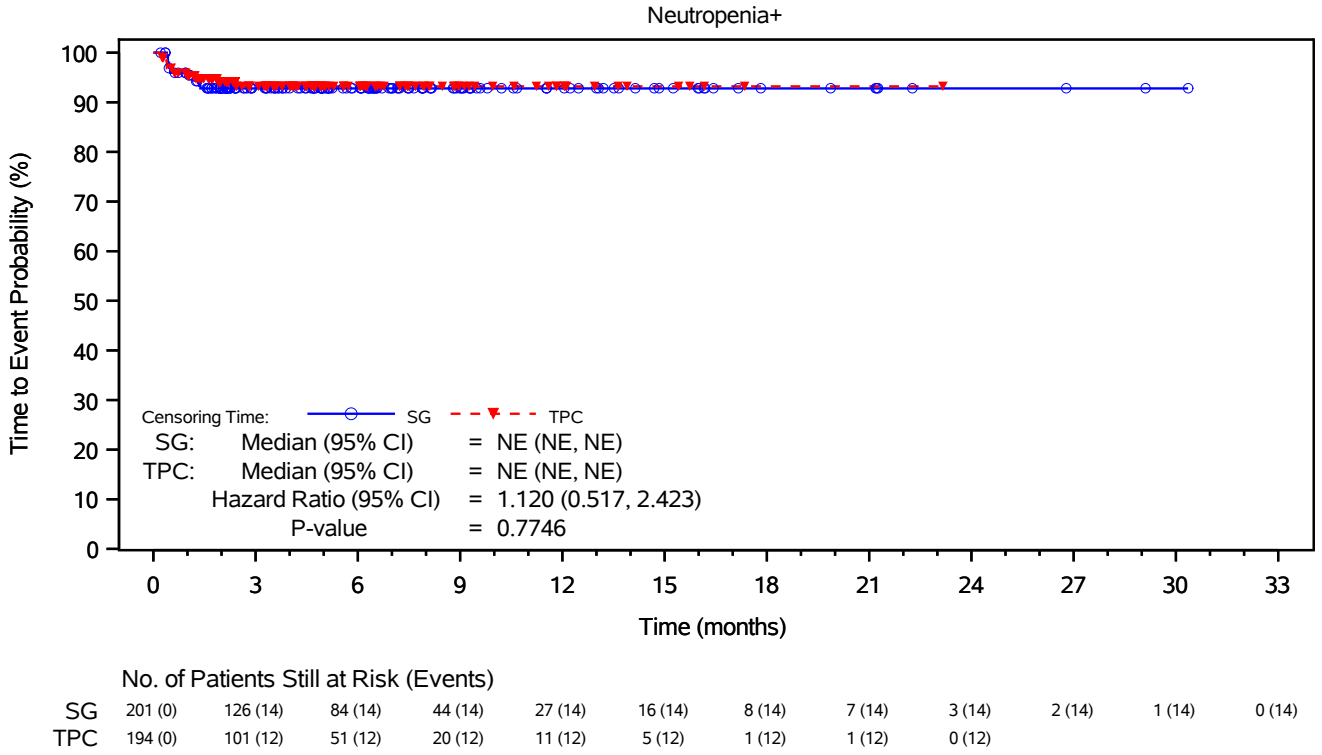

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Figure 15.11.4.3: KM Plot for Time to the First Serious TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

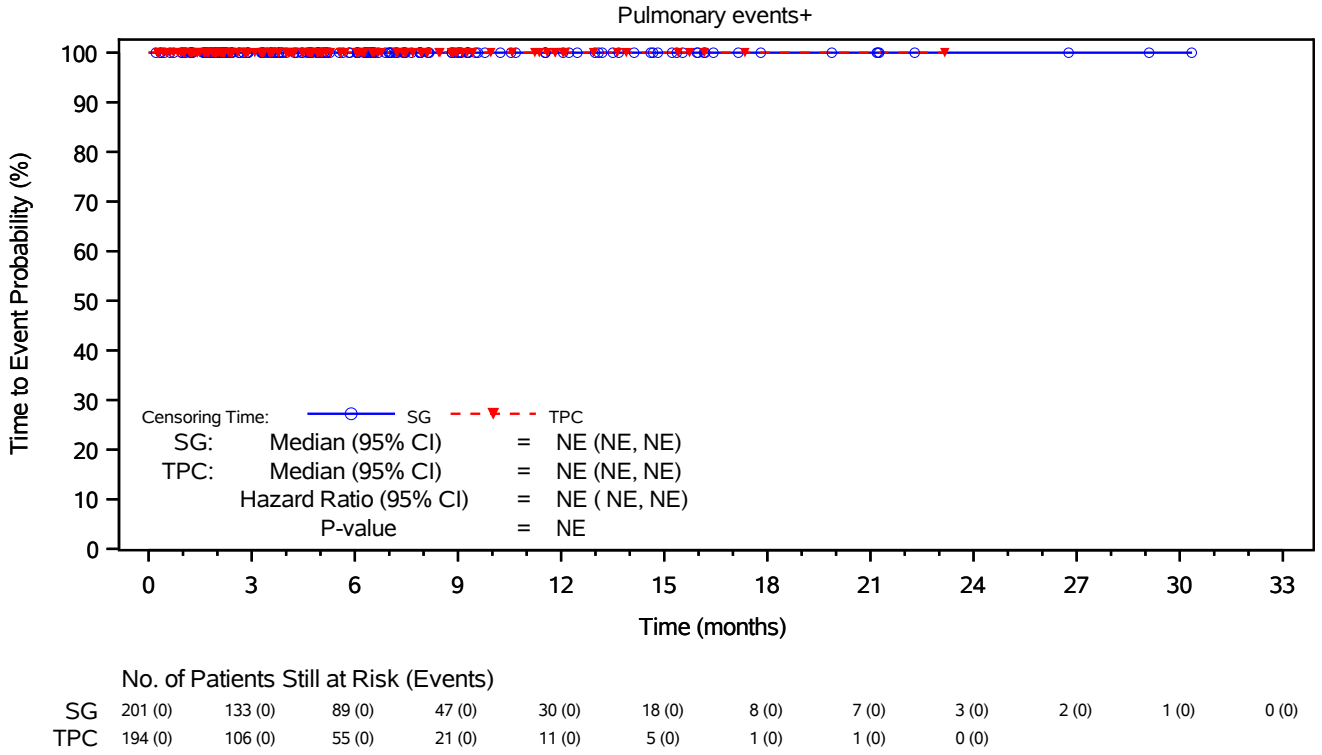

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Patients With Events (%)	125 (62.2%)	86 (44.3%)	
Patients Without Events (Censored) (%)	76 (37.8%)	108 (55.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.9, 2.3)	5.8 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.568 (1.190, 2.066)
p-value			0.0013

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Patients With Events (%)	19 (9.5%)	3 (1.5%)	
Patients Without Events (Censored) (%)	182 (90.5%)	191 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.953 (1.759, 20.141)
p-value			0.0011

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Patients With Events (%)	12 (6.0%)	11 (5.7%)	
Patients Without Events (Censored) (%)	189 (94.0%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.054 (0.464, 2.393)
p-value			0.9016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Patients With Events (%)	3 (1.5%)	1 (0.5%)	
Patients Without Events (Censored) (%)	198 (98.5%)	193 (99.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.435 (0.248, 23.882)
p-value			0.4308

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Patients With Events (%)	21 (10.4%)	8 (4.1%)	
Patients Without Events (Censored) (%)	180 (89.6%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.077 (0.907, 4.756)
p-value			0.0774

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Patients With Events (%)	6 (3.0%)	7 (3.6%)	
Patients Without Events (Censored) (%)	195 (97.0%)	187 (96.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.636 (0.210, 1.925)
p-value			0.4195

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Patients With Events (%)	111 (55.2%)	77 (39.7%)	
Patients Without Events (Censored) (%)	90 (44.8%)	117 (60.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (1.0, 4.6)	9.6 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.548 (1.154, 2.075)
p-value			0.0033

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.5: Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Pulmonary events+			
Patients With Events (%)	0	1 (0.5%)	
Patients Without Events (Censored) (%)	201 (100.0%)	193 (99.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3083

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
Time to event is the time (months) from the 1st dose date to the event date or 30 days after treatment, death date, or last contact, which is earlier
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
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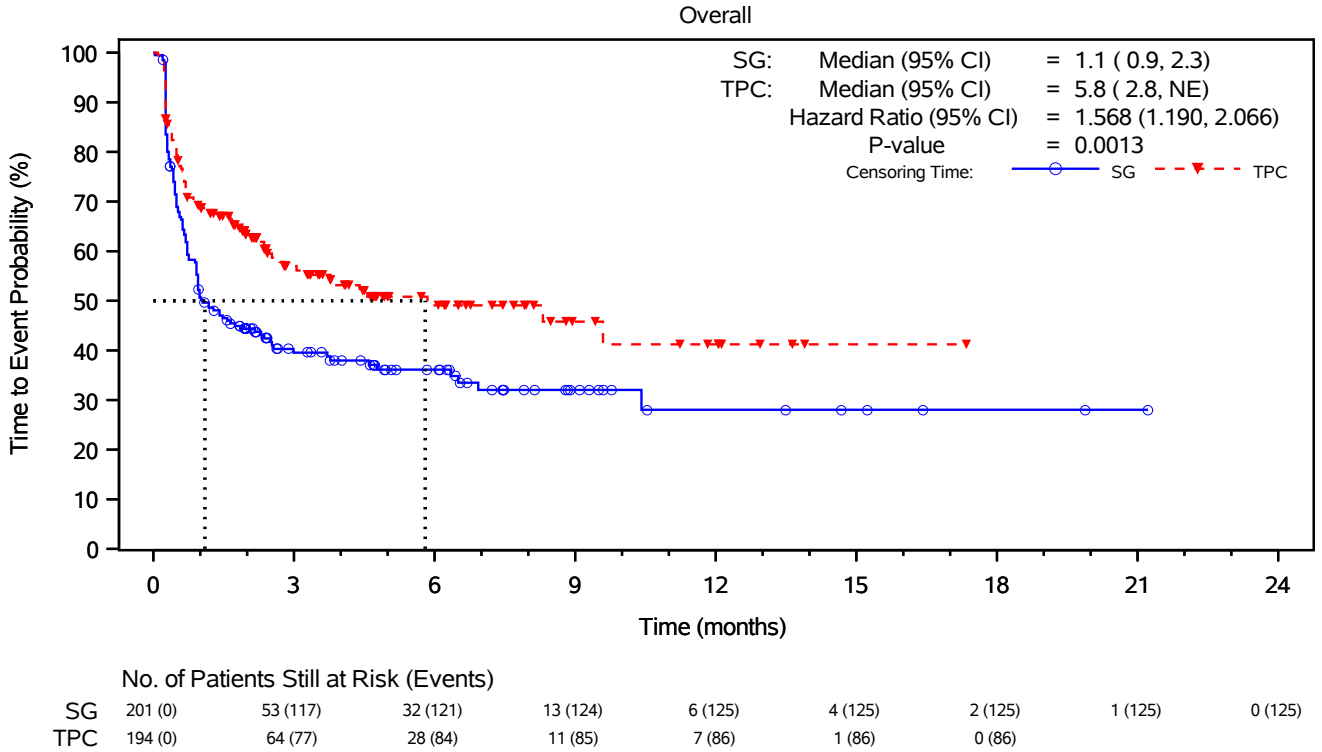
Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

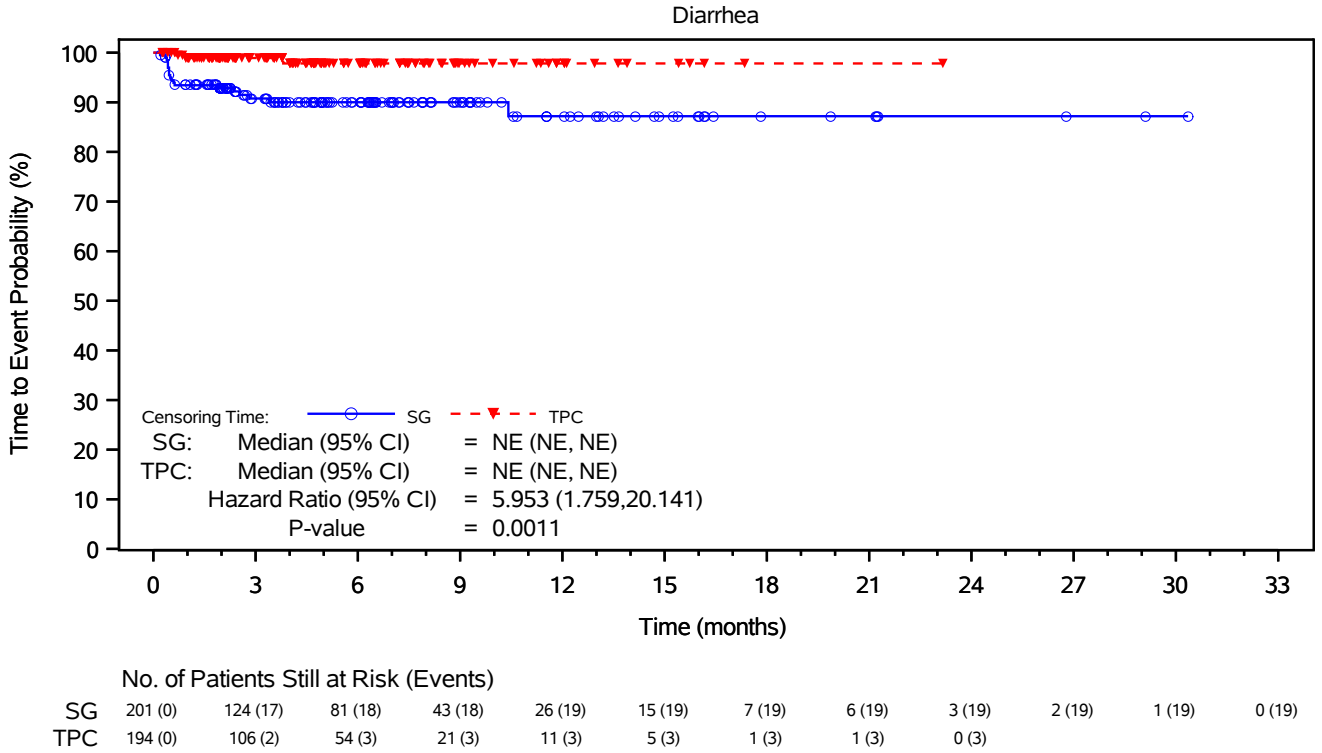

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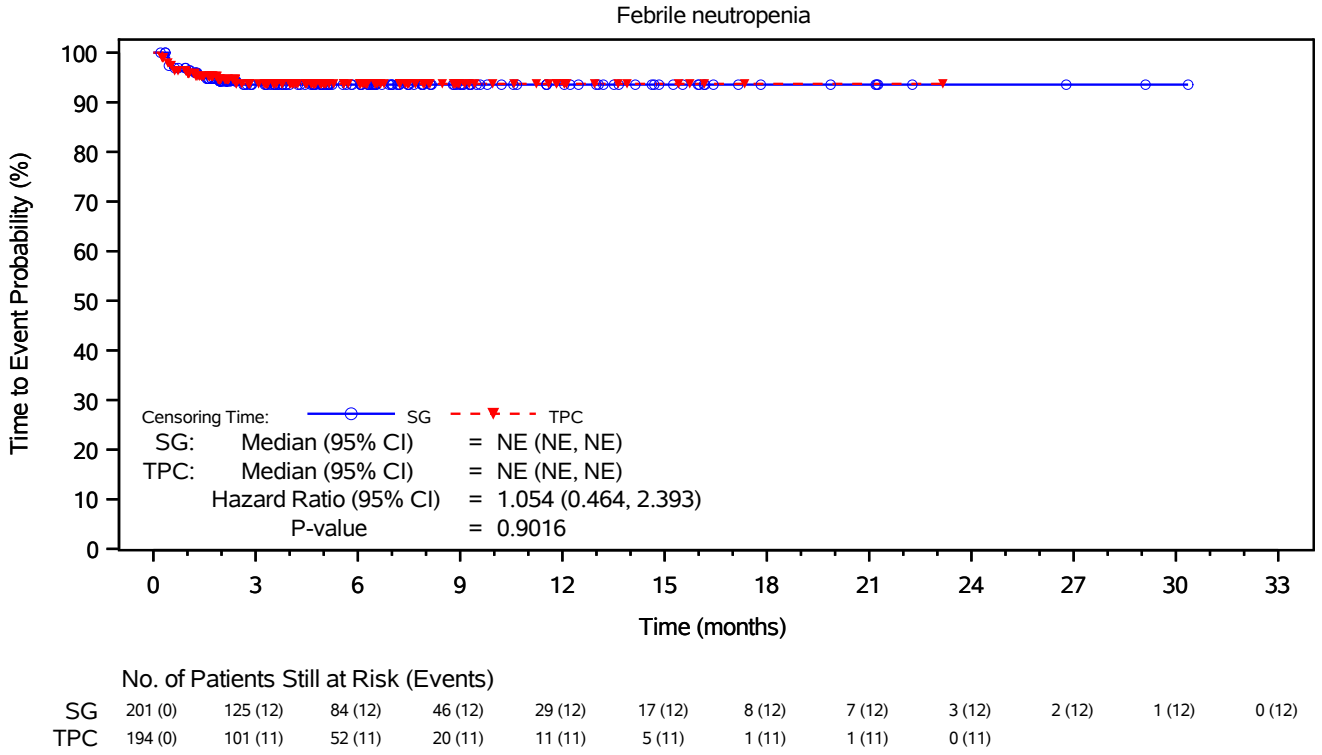
Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



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Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine

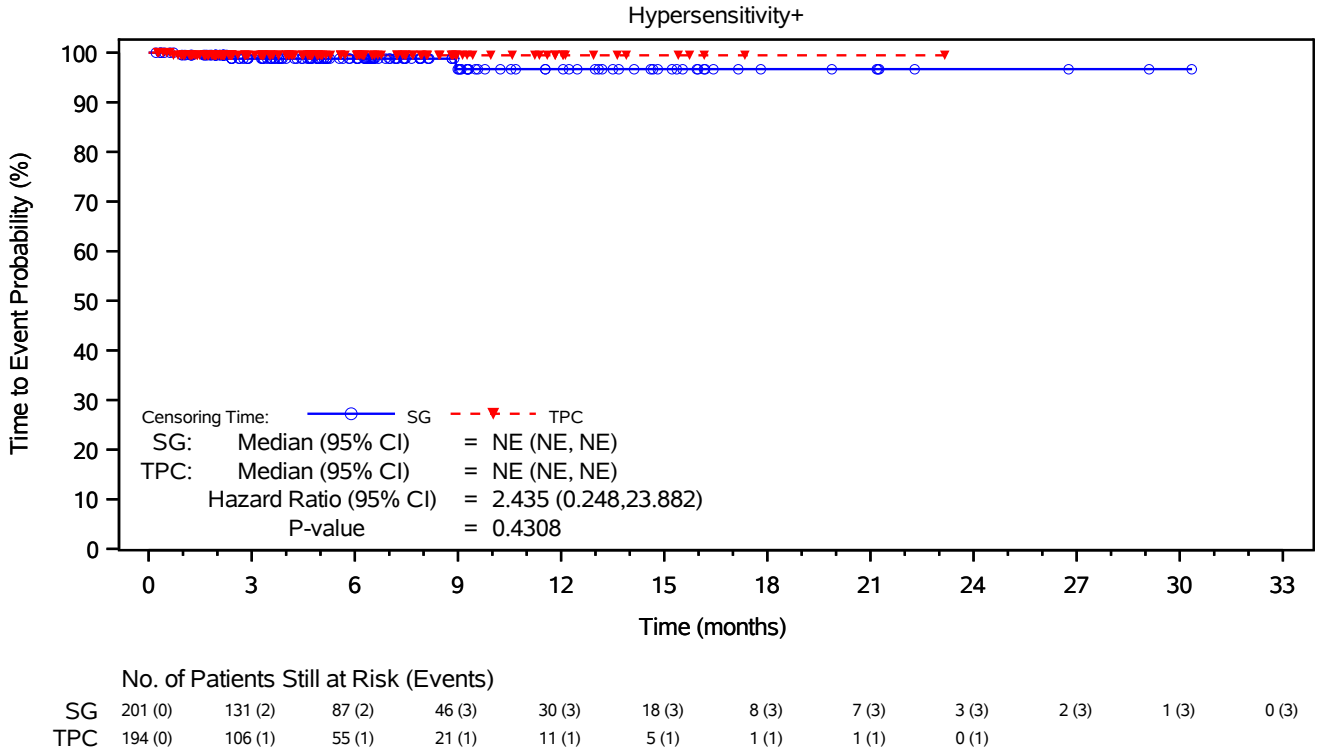

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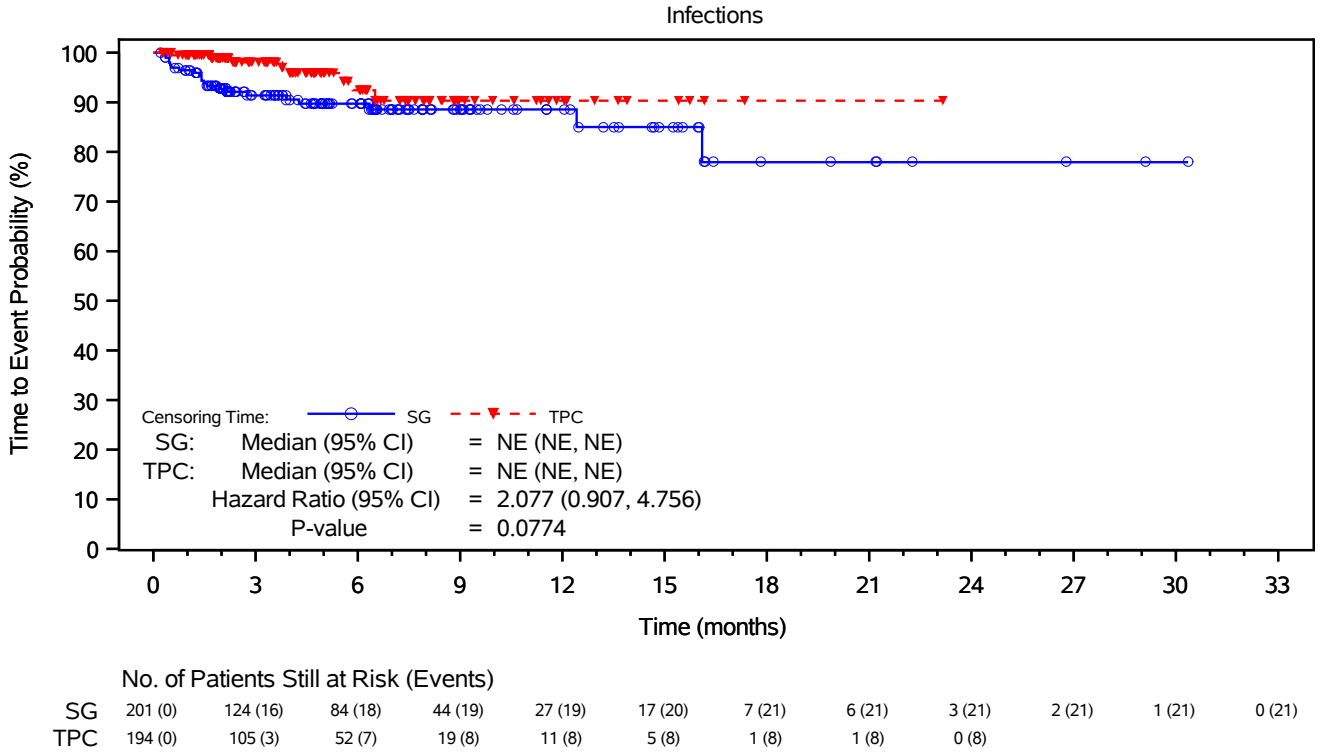
Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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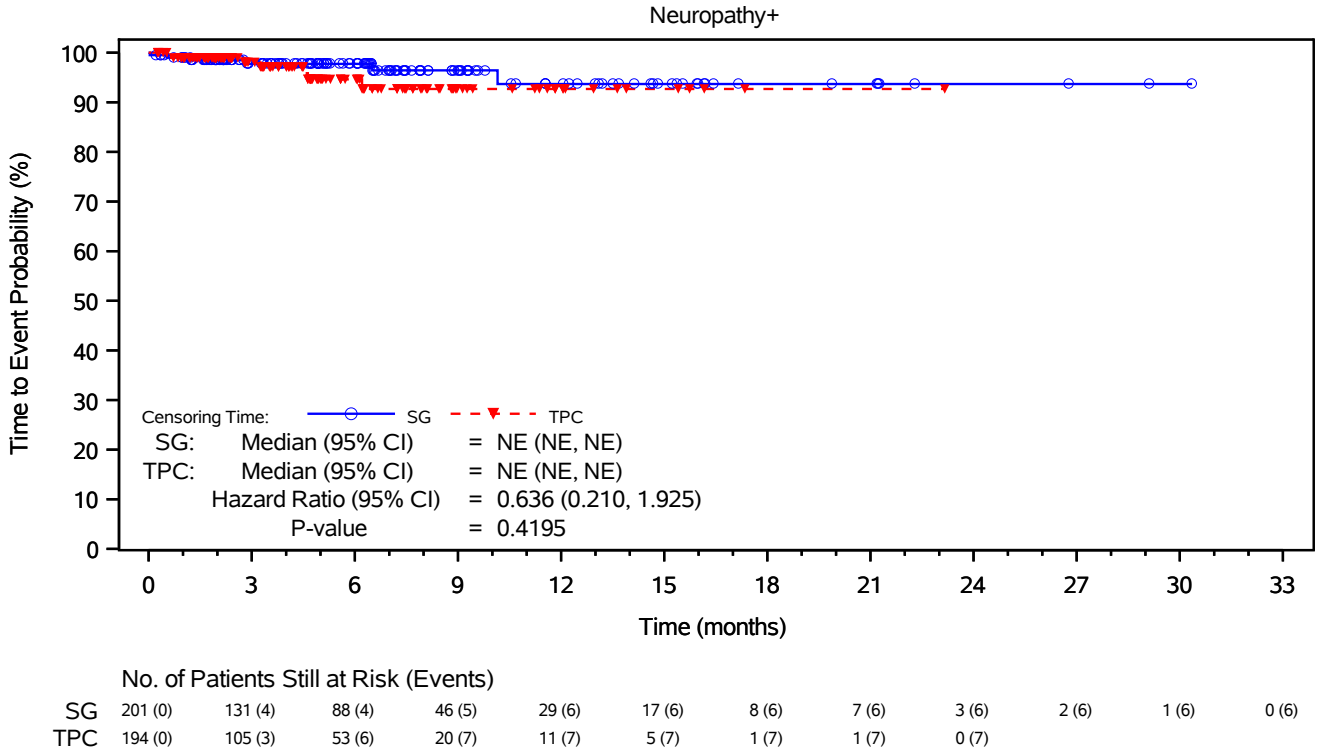
Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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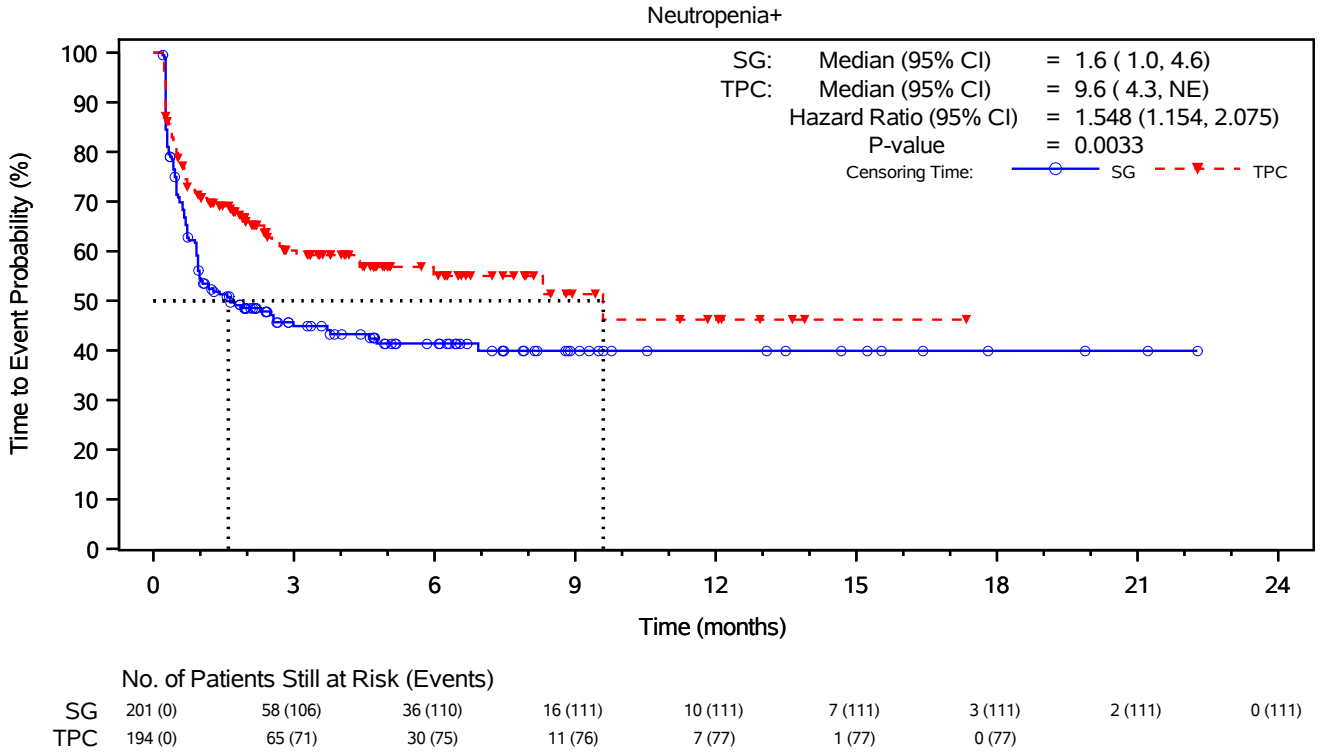
Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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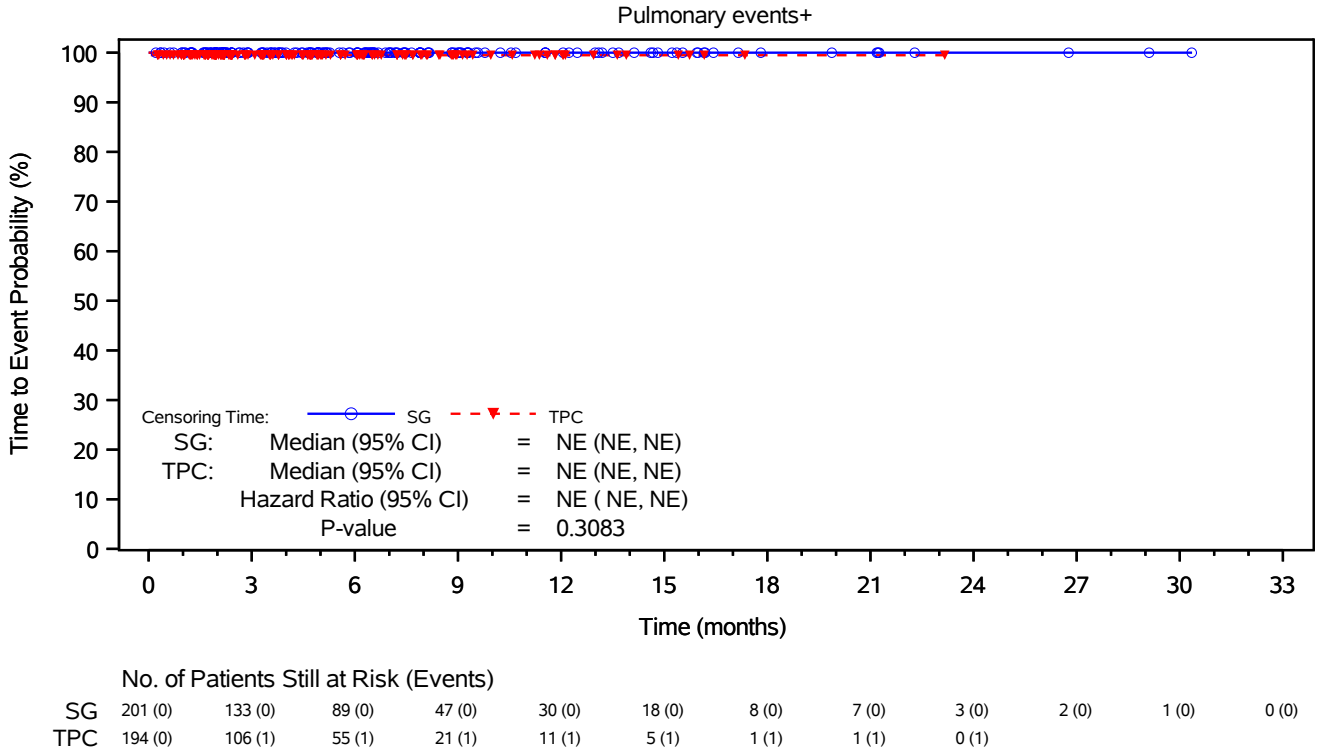
Figure 15.11.4.5: KM Plot for Time to the First Grade 3 or Higher TEAE of Special Interest
Safety Population
Excluding participants pre-selected to Gemcitabine



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NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Anhang 4-G 7.4: UE nach SOC und PT

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Patients With Events (%)	165 (82.1%)	118 (60.8%)	
Patients Without Events (Censored) (%)	36 (17.9%)	76 (39.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 0.7)	1.7 (0.7, 2.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.690 (1.328, 2.152)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Patients With Events (%)	70 (34.8%)	45 (23.2%)	
Patients Without Events (Censored) (%)	131 (65.2%)	149 (76.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.9, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.459 (1.000, 2.129)
p-value			0.0493

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Febrile neutropenia			
Patients With Events (%)	12 (6.0%)	11 (5.7%)	
Patients Without Events (Censored) (%)	189 (94.0%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.054 (0.464, 2.393)
p-value			0.9016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Leukopenia			
Patients With Events (%)	31 (15.4%)	18 (9.3%)	
Patients Without Events (Censored) (%)	170 (84.6%)	176 (90.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.626 (0.907, 2.915)
p-value			0.1022

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Lymphopenia			
Patients With Events (%)	25 (12.4%)	18 (9.3%)	
Patients Without Events (Censored) (%)	176 (87.6%)	176 (90.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.286 (0.699, 2.365)
p-value			0.4148

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Patients With Events (%)	142 (70.6%)	101 (52.1%)	
Patients Without Events (Censored) (%)	59 (29.4%)	93 (47.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.7 (1.6, 6.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.597 (1.233, 2.067)
p-value			0.0003

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Patients With Events (%)	12 (6.0%)	21 (10.8%)	
Patients Without Events (Censored) (%)	189 (94.0%)	173 (89.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.493 (0.242, 1.005)
p-value			0.0472

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Cardiac disorders			
Patients With Events (%)	15 (7.5%)	15 (7.7%)	
Patients Without Events (Censored) (%)	186 (92.5%)	179 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.812 (0.394, 1.675)
p-value			0.5726

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Ear and labyrinth disorders			
Patients With Events (%)	11 (5.5%)	11 (5.7%)	
Patients Without Events (Censored) (%)	190 (94.5%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.853 (0.367, 1.982)
p-value			0.7117

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Eye disorders			
Patients With Events (%)	17 (8.5%)	16 (8.2%)	
Patients Without Events (Censored) (%)	184 (91.5%)	178 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.4, NE)	20.8 (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.803 (0.397, 1.624)
p-value			0.5426

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Patients With Events (%)	186 (92.5%)	138 (71.1%)	
Patients Without Events (Censored) (%)	15 (7.5%)	56 (28.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.6, 1.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.949 (1.555, 2.444)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Abdominal distension			
Patients With Events (%)	15 (7.5%)	7 (3.6%)	
Patients Without Events (Censored) (%)	186 (92.5%)	187 (96.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.901 (0.771, 4.689)
p-value			0.1563

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Abdominal pain			
Patients With Events (%)	44 (21.9%)	30 (15.5%)	
Patients Without Events (Censored) (%)	157 (78.1%)	164 (84.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.408 (0.881, 2.249)
p-value			0.1538

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Abdominal pain upper			
Patients With Events (%)	21 (10.4%)	12 (6.2%)	
Patients Without Events (Censored) (%)	180 (89.6%)	182 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.405 (0.682, 2.893)
p-value			0.3550

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Constipation			
Patients With Events (%)	67 (33.3%)	48 (24.7%)	
Patients Without Events (Censored) (%)	134 (66.7%)	146 (75.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.298 (0.894, 1.884)
p-value			0.1694

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Patients With Events (%)	120 (59.7%)	49 (25.3%)	
Patients Without Events (Censored) (%)	81 (40.3%)	145 (74.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.3, 3.3)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.077 (2.196, 4.311)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Dry mouth			
Patients With Events (%)	13 (6.5%)	5 (2.6%)	
Patients Without Events (Censored) (%)	188 (93.5%)	189 (97.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.019 (0.708, 5.754)
p-value			0.1798

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Dyspepsia			
Patients With Events (%)	14 (7.0%)	5 (2.6%)	
Patients Without Events (Censored) (%)	187 (93.0%)	189 (97.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.425 (0.872, 6.742)
p-value			0.0792

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Gastrooesophageal reflux disease			
Patients With Events (%)	10 (5.0%)	8 (4.1%)	
Patients Without Events (Censored) (%)	191 (95.0%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.014 (0.396, 2.594)
p-value			0.9765

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Patients With Events (%)	120 (59.7%)	64 (33.0%)	
Patients Without Events (Censored) (%)	81 (40.3%)	130 (67.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.8, 2.6)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.189 (1.611, 2.974)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Stomatitis			
Patients With Events (%)	17 (8.5%)	17 (8.8%)	
Patients Without Events (Censored) (%)	184 (91.5%)	177 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.912 (0.465, 1.792)
p-value			0.7919

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Patients With Events (%)	50 (24.9%)	27 (13.9%)	
Patients Without Events (Censored) (%)	151 (75.1%)	167 (86.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.680 (1.048, 2.693)
p-value			0.0292

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - General disorders and administration site conditions			
Patients With Events (%)	150 (74.6%)	134 (69.1%)	
Patients Without Events (Censored) (%)	51 (25.4%)	60 (30.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.4, 0.8)	1.1 (0.7, 1.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.185 (0.934, 1.504)
p-value			0.1670

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Asthenia			
Patients With Events (%)	47 (23.4%)	39 (20.1%)	
Patients Without Events (Censored) (%)	154 (76.6%)	155 (79.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.145 (0.748, 1.753)
p-value			0.5317

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Fatigue			
Patients With Events (%)	78 (38.8%)	66 (34.0%)	
Patients Without Events (Censored) (%)	123 (61.2%)	128 (66.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.7 (9.1, NE)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.095 (0.786, 1.525)
p-value			0.5946

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Mucosal inflammation			
Patients With Events (%)	19 (9.5%)	13 (6.7%)	
Patients Without Events (Censored) (%)	182 (90.5%)	181 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.240 (0.609, 2.525)
p-value			0.5515

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Oedema peripheral			
Patients With Events (%)	12 (6.0%)	9 (4.6%)	
Patients Without Events (Censored) (%)	189 (94.0%)	185 (95.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.973 (0.402, 2.353)
p-value			0.9526

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pain			
Patients With Events (%)	10 (5.0%)	9 (4.6%)	
Patients Without Events (Censored) (%)	191 (95.0%)	185 (95.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (24.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.776 (0.298, 2.022)
p-value			0.6027

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pyrexia			
Patients With Events (%)	36 (17.9%)	32 (16.5%)	
Patients Without Events (Censored) (%)	165 (82.1%)	162 (83.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (21.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.884 (0.544, 1.436)
p-value			0.6180

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Hepatobiliary disorders			
Patients With Events (%)	21 (10.4%)	17 (8.8%)	
Patients Without Events (Censored) (%)	180 (89.6%)	177 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	22.2 (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.049 (0.552, 1.993)
p-value			0.8869

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Infections and infestations			
Patients With Events (%)	76 (37.8%)	55 (28.4%)	
Patients Without Events (Censored) (%)	125 (62.2%)	139 (71.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (6.4, 15.8)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.139 (0.802, 1.619)
p-value			0.4680

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Urinary tract infection			
Patients With Events (%)	17 (8.5%)	18 (9.3%)	
Patients Without Events (Censored) (%)	184 (91.5%)	176 (90.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (21.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.737 (0.373, 1.455)
p-value			0.3775

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Injury, poisoning and procedural complications			
Patients With Events (%)	19 (9.5%)	17 (8.8%)	
Patients Without Events (Censored) (%)	182 (90.5%)	177 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (18.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.745 (0.377, 1.475)
p-value			0.3963

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Investigations			
Patients With Events (%)	64 (31.8%)	61 (31.4%)	
Patients Without Events (Censored) (%)	137 (68.2%)	133 (68.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (10.6, NE)	10.0 (5.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.921 (0.646, 1.314)
p-value			0.6504

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alanine aminotransferase increased			
Patients With Events (%)	23 (11.4%)	13 (6.7%)	
Patients Without Events (Censored) (%)	178 (88.6%)	181 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (21.5, NE)	18.7 (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.428 (0.713, 2.860)
p-value			0.3133

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Aspartate aminotransferase increased			
Patients With Events (%)	25 (12.4%)	22 (11.3%)	
Patients Without Events (Censored) (%)	176 (87.6%)	172 (88.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.4, NE)	16.7 (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.925 (0.517, 1.657)
p-value			0.7950

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Blood alkaline phosphatase increased			
Patients With Events (%)	17 (8.5%)	17 (8.8%)	
Patients Without Events (Censored) (%)	184 (91.5%)	177 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (19.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.744 (0.371, 1.494)
p-value			0.4052

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Blood bilirubin increased			
Patients With Events (%)	7 (3.5%)	12 (6.2%)	
Patients Without Events (Censored) (%)	194 (96.5%)	182 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.565 (0.222, 1.439)
p-value			0.2241

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Gamma-glutamyltransferase increased			
Patients With Events (%)	11 (5.5%)	6 (3.1%)	
Patients Without Events (Censored) (%)	190 (94.5%)	188 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (21.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.239 (0.438, 3.505)
p-value			0.6860

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Weight decreased			
Patients With Events (%)	12 (6.0%)	11 (5.7%)	
Patients Without Events (Censored) (%)	189 (94.0%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.810 (0.349, 1.881)
p-value			0.6238

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Metabolism and nutrition disorders			
Patients With Events (%)	88 (43.8%)	69 (35.6%)	
Patients Without Events (Censored) (%)	113 (56.2%)	125 (64.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	11.6 (4.8, NE)	NE (5.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.197 (0.872, 1.644)
p-value			0.2545

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Decreased appetite			
Patients With Events (%)	47 (23.4%)	44 (22.7%)	
Patients Without Events (Censored) (%)	154 (76.6%)	150 (77.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.4 (28.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.958 (0.633, 1.450)
p-value			0.8406

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Patients With Events (%)	6 (3.0%)	13 (6.7%)	
Patients Without Events (Censored) (%)	195 (97.0%)	181 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.369 (0.138, 0.981)
p-value			0.0379

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Patients With Events (%)	24 (11.9%)	8 (4.1%)	
Patients Without Events (Censored) (%)	177 (88.1%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.644 (1.182, 5.916)
p-value			0.0139

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypomagnesaemia			
Patients With Events (%)	13 (6.5%)	7 (3.6%)	
Patients Without Events (Censored) (%)	188 (93.5%)	187 (96.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.676 (0.666, 4.217)
p-value			0.2671

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Musculoskeletal and connective tissue disorders			
Patients With Events (%)	84 (41.8%)	85 (43.8%)	
Patients Without Events (Censored) (%)	117 (58.2%)	109 (56.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.0 (4.5, NE)	4.3 (3.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.752 (0.552, 1.025)
p-value			0.0697

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Arthralgia			
Patients With Events (%)	27 (13.4%)	25 (12.9%)	
Patients Without Events (Censored) (%)	174 (86.6%)	169 (87.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (19.4, NE)	19.3 (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.817 (0.468, 1.425)
p-value			0.4744

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Back pain			
Patients With Events (%)	27 (13.4%)	24 (12.4%)	
Patients Without Events (Censored) (%)	174 (86.6%)	170 (87.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.913 (0.520, 1.603)
p-value			0.7518

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Bone pain			
Patients With Events (%)	13 (6.5%)	16 (8.2%)	
Patients Without Events (Censored) (%)	188 (93.5%)	178 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.615 (0.292, 1.295)
p-value			0.1961

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Muscle spasms			
Patients With Events (%)	15 (7.5%)	10 (5.2%)	
Patients Without Events (Censored) (%)	186 (92.5%)	184 (94.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.216 (0.542, 2.730)
p-value			0.6343

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Muscular weakness			
Patients With Events (%)	10 (5.0%)	8 (4.1%)	
Patients Without Events (Censored) (%)	191 (95.0%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.904 (0.350, 2.332)
p-value			0.8348

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Patients With Events (%)	11 (5.5%)	17 (8.8%)	
Patients Without Events (Censored) (%)	190 (94.5%)	177 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.421 (0.189, 0.940)
p-value			0.0299

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pain in extremity			
Patients With Events (%)	12 (6.0%)	13 (6.7%)	
Patients Without Events (Censored) (%)	189 (94.0%)	181 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.712 (0.322, 1.574)
p-value			0.3991

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Patients With Events (%)	74 (36.8%)	84 (43.3%)	
Patients Without Events (Censored) (%)	127 (63.2%)	110 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.1, NE)	3.9 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.718 (0.524, 0.984)
p-value			0.0393

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Dizziness			
Patients With Events (%)	18 (9.0%)	10 (5.2%)	
Patients Without Events (Censored) (%)	183 (91.0%)	184 (94.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (19.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.538 (0.702, 3.370)
p-value			0.2787

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Dysgeusia			
Patients With Events (%)	10 (5.0%)	10 (5.2%)	
Patients Without Events (Censored) (%)	191 (95.0%)	184 (94.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.840 (0.348, 2.030)
p-value			0.6956

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Headache			
Patients With Events (%)	30 (14.9%)	27 (13.9%)	
Patients Without Events (Censored) (%)	171 (85.1%)	167 (86.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.982 (0.582, 1.657)
p-value			0.9457

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Patients With Events (%)	9 (4.5%)	18 (9.3%)	
Patients Without Events (Censored) (%)	192 (95.5%)	176 (90.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.364 (0.161, 0.821)
p-value			0.0114

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Patients With Events (%)	7 (3.5%)	14 (7.2%)	
Patients Without Events (Censored) (%)	194 (96.5%)	180 (92.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.358 (0.137, 0.933)
p-value			0.0285

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Peripheral sensory neuropathy			
Patients With Events (%)	9 (4.5%)	14 (7.2%)	
Patients Without Events (Censored) (%)	192 (95.5%)	180 (92.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.504 (0.217, 1.173)
p-value			0.1051

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Psychiatric disorders			
Patients With Events (%)	25 (12.4%)	27 (13.9%)	
Patients Without Events (Censored) (%)	176 (87.6%)	167 (86.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (11.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.703 (0.402, 1.229)
p-value			0.2136

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Insomnia			
Patients With Events (%)	12 (6.0%)	12 (6.2%)	
Patients Without Events (Censored) (%)	189 (94.0%)	182 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.832 (0.369, 1.876)
p-value			0.6568

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Renal and urinary disorders			
Patients With Events (%)	17 (8.5%)	18 (9.3%)	
Patients Without Events (Censored) (%)	184 (91.5%)	176 (90.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.801 (0.406, 1.577)
p-value			0.5191

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Reproductive system and breast disorders			
Patients With Events (%)	10 (5.0%)	5 (2.6%)	
Patients Without Events (Censored) (%)	191 (95.0%)	189 (97.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.779 (0.606, 5.224)
p-value			0.2883

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Patients With Events (%)	86 (42.8%)	59 (30.4%)	
Patients Without Events (Censored) (%)	115 (57.2%)	135 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.5 (3.9, NE)	10.1 (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.455 (1.038, 2.039)
p-value			0.0295

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Cough			
Patients With Events (%)	23 (11.4%)	13 (6.7%)	
Patients Without Events (Censored) (%)	178 (88.6%)	181 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.489 (0.752, 2.948)
p-value			0.2523

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Dyspnoea			
Patients With Events (%)	40 (19.9%)	29 (14.9%)	
Patients Without Events (Censored) (%)	161 (80.1%)	165 (85.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.240 (0.767, 2.004)
p-value			0.3810

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Patients With Events (%)	17 (8.5%)	4 (2.1%)	
Patients Without Events (Censored) (%)	184 (91.5%)	190 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.737 (1.249, 11.180)
p-value			0.0114

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Rhinorrhoea			
Patients With Events (%)	11 (5.5%)	4 (2.1%)	
Patients Without Events (Censored) (%)	190 (94.5%)	190 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.175 (0.684, 6.915)
p-value			0.1770

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Patients With Events (%)	120 (59.7%)	79 (40.7%)	
Patients Without Events (Censored) (%)	81 (40.3%)	115 (59.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.3)	5.7 (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.806 (1.355, 2.409)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Patients With Events (%)	98 (48.8%)	45 (23.2%)	
Patients Without Events (Censored) (%)	103 (51.2%)	149 (76.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.8 (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.535 (1.778, 3.615)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Dry skin			
Patients With Events (%)	13 (6.5%)	8 (4.1%)	
Patients Without Events (Censored) (%)	188 (93.5%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.188 (0.487, 2.902)
p-value			0.7047

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Patients With Events (%)	4 (2.0%)	14 (7.2%)	
Patients Without Events (Censored) (%)	197 (98.0%)	180 (92.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.185 (0.053, 0.647)
p-value			0.0031

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Patients With Events (%)	24 (11.9%)	4 (2.1%)	
Patients Without Events (Censored) (%)	177 (88.1%)	190 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.510 (1.906, 15.927)
p-value			0.0004

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Rash			
Patients With Events (%)	16 (8.0%)	9 (4.6%)	
Patients Without Events (Censored) (%)	185 (92.0%)	185 (95.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.586 (0.697, 3.607)
p-value			0.2680

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Vascular disorders			
Patients With Events (%)	31 (15.4%)	27 (13.9%)	
Patients Without Events (Censored) (%)	170 (84.6%)	167 (86.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.003 (0.595, 1.692)
p-value			0.9927

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
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Table 15.11.7.1: Time to the First Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypertension			
Patients With Events (%)	12 (6.0%)	9 (4.6%)	
Patients Without Events (Censored) (%)	189 (94.0%)	185 (95.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.186 (0.497, 2.832)
p-value			0.7016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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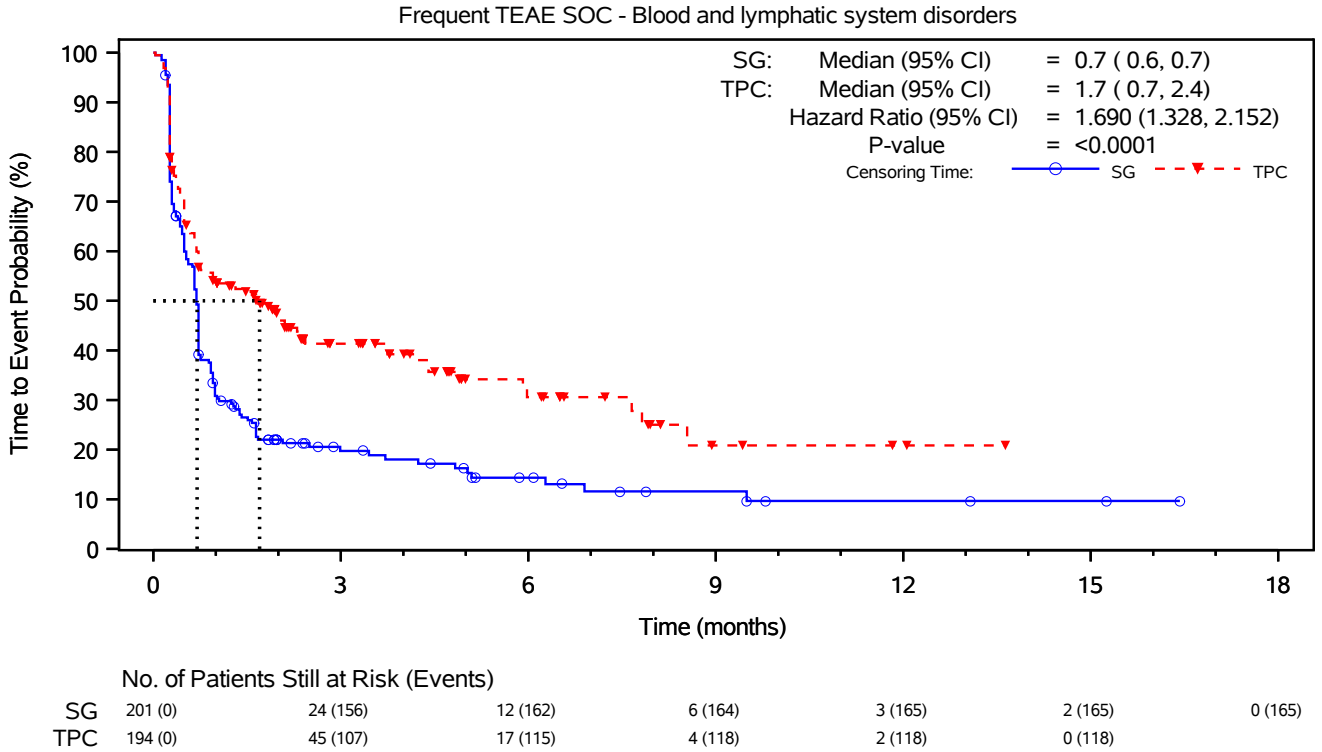
Figure 15.11.7.1: KM Plot for Time to the First Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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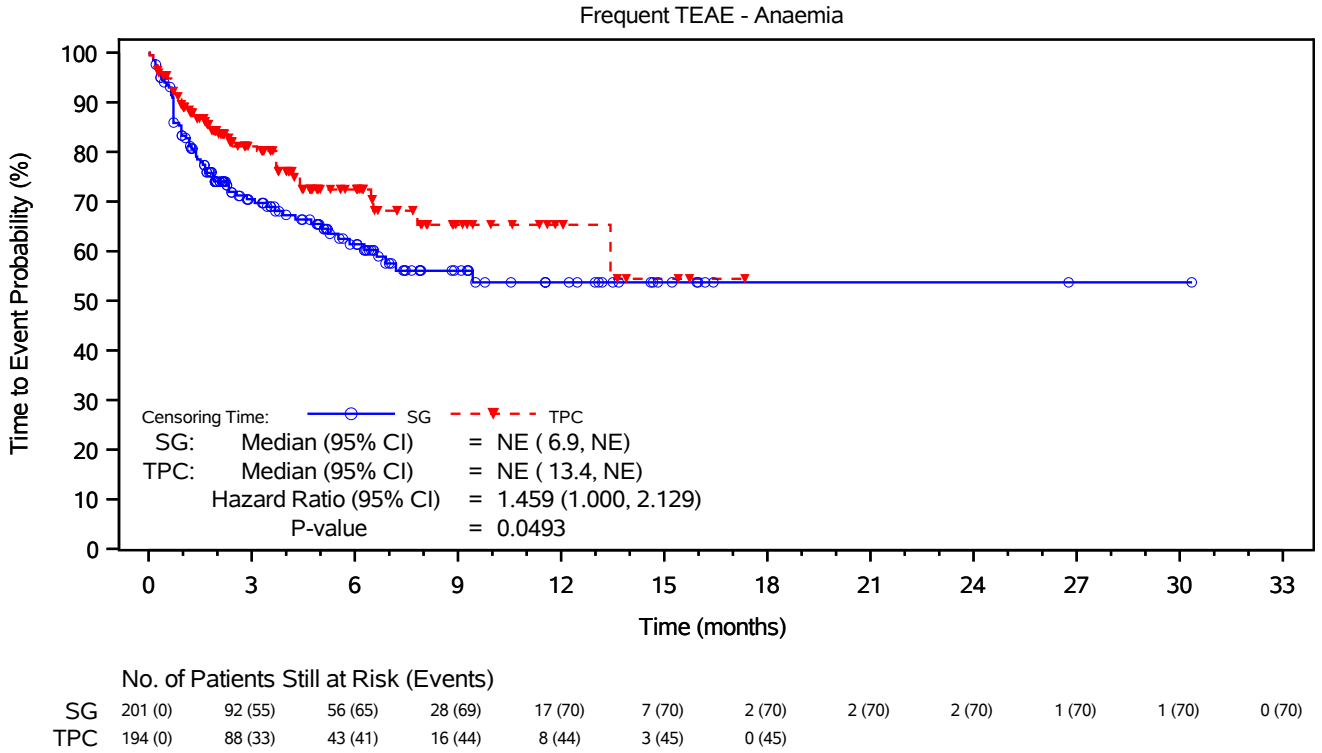

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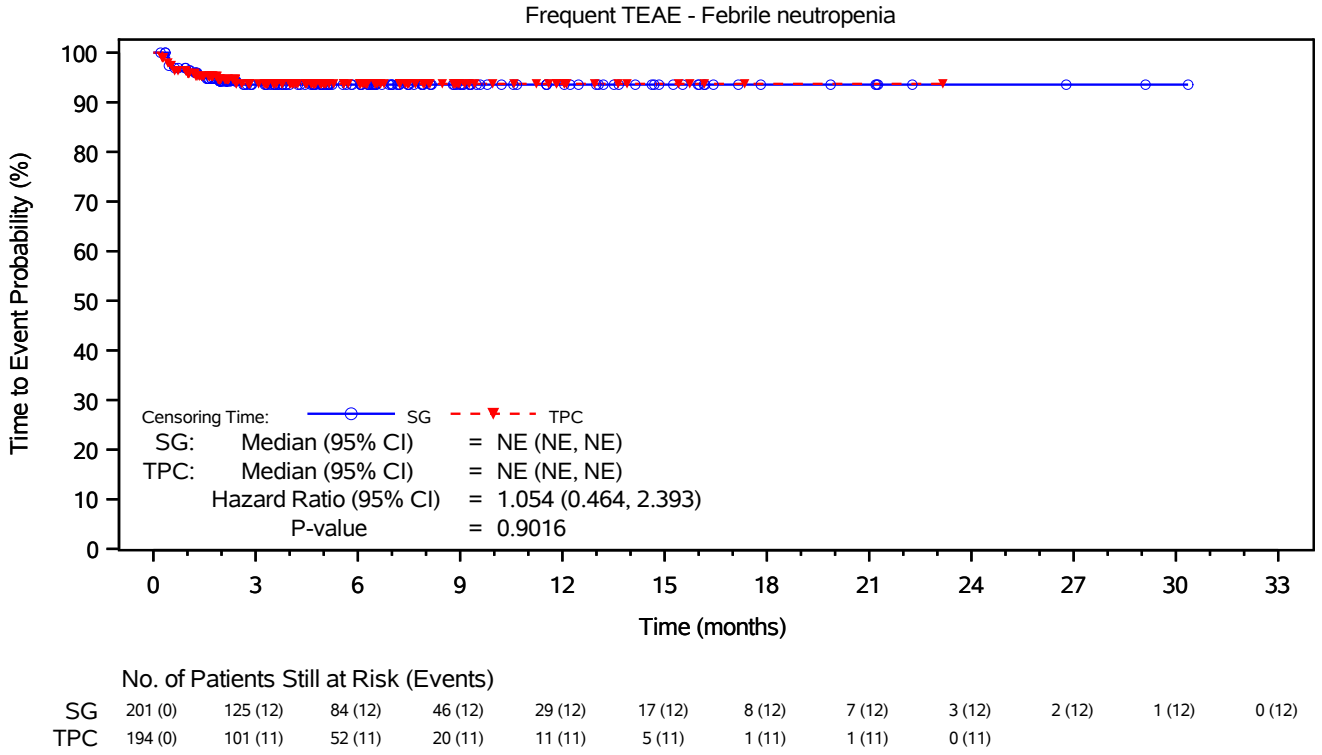

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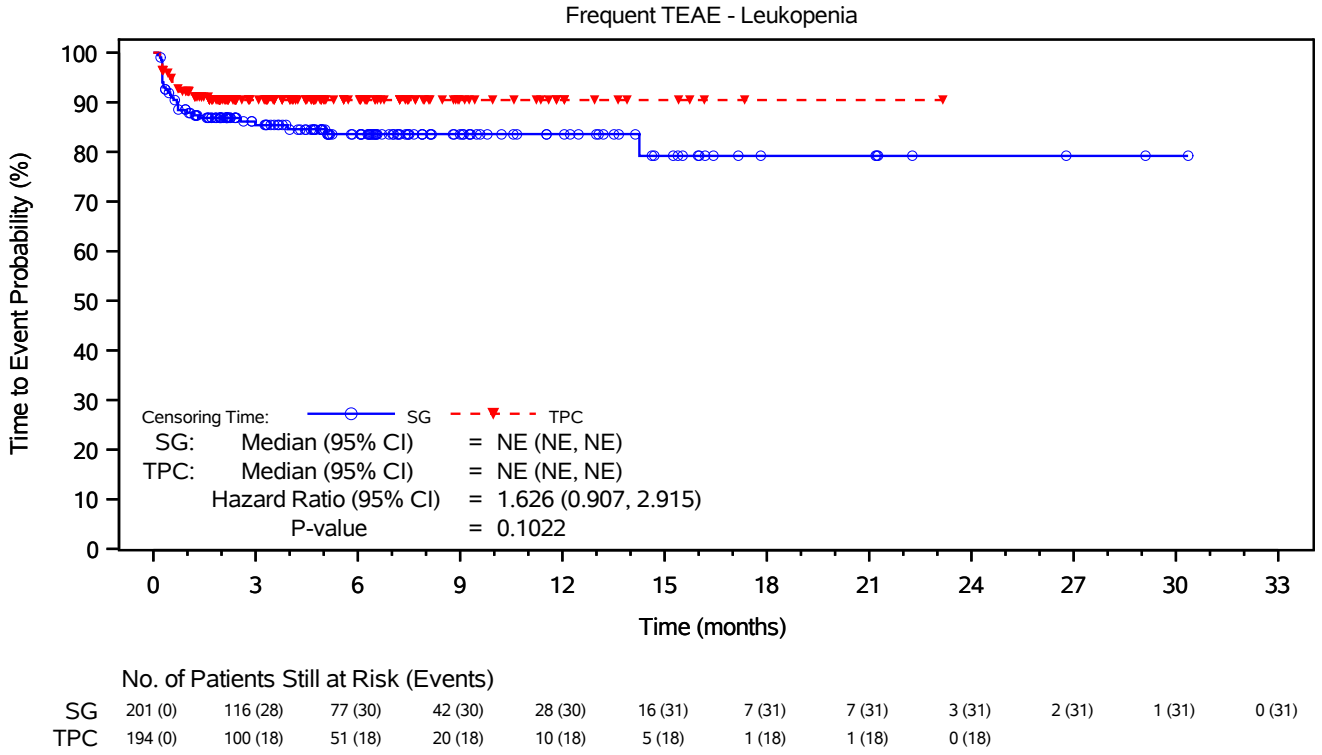

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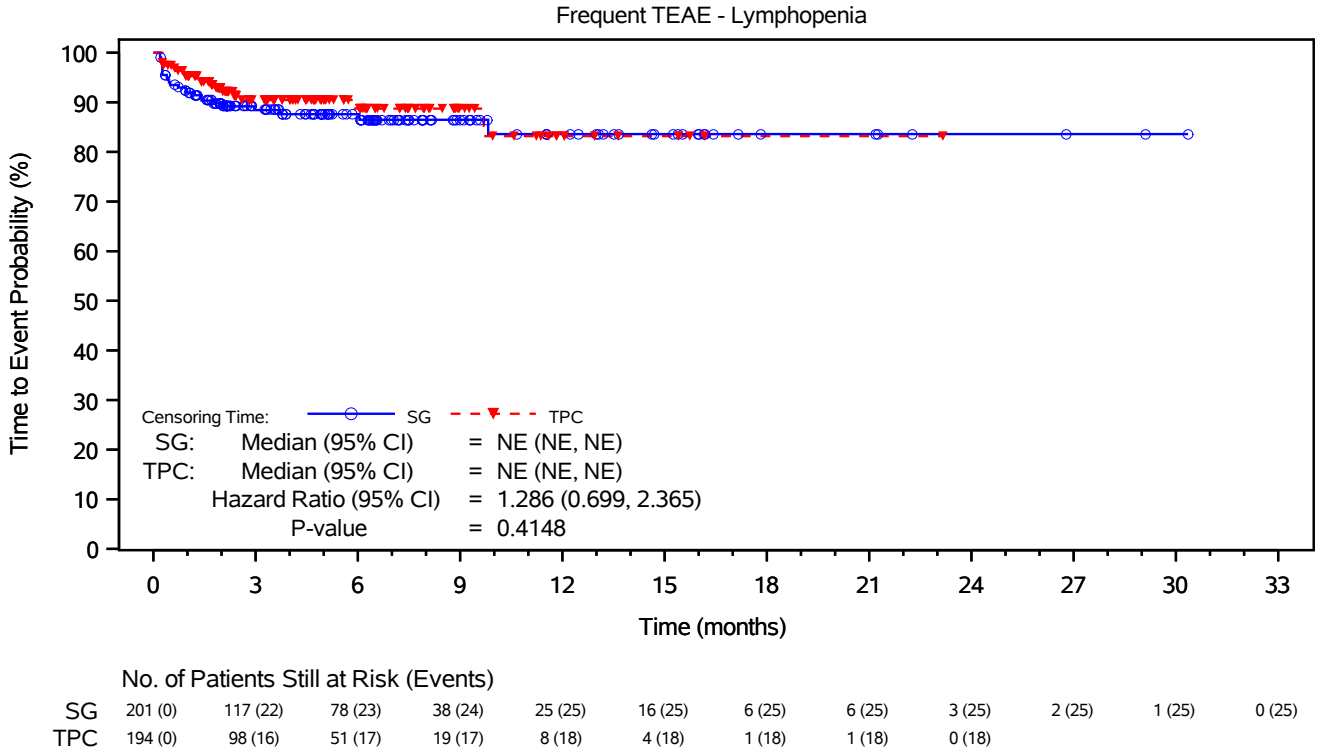

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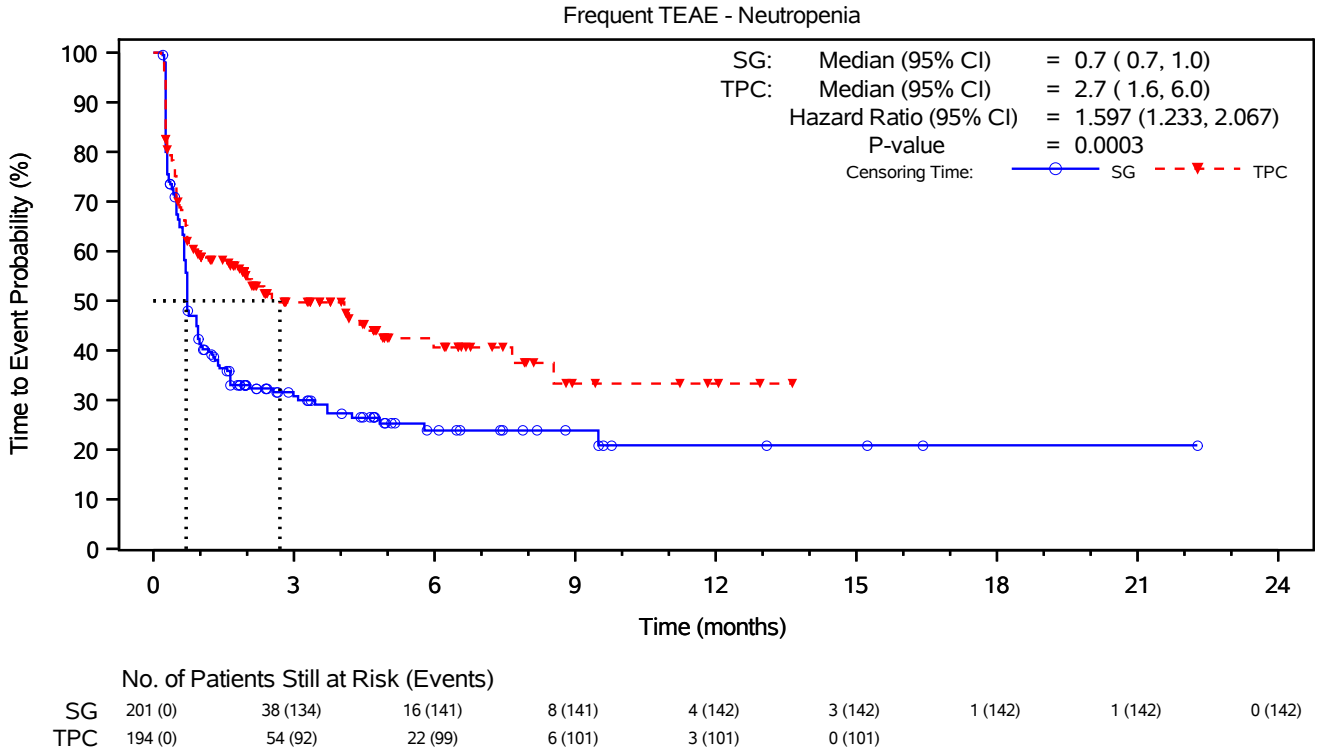

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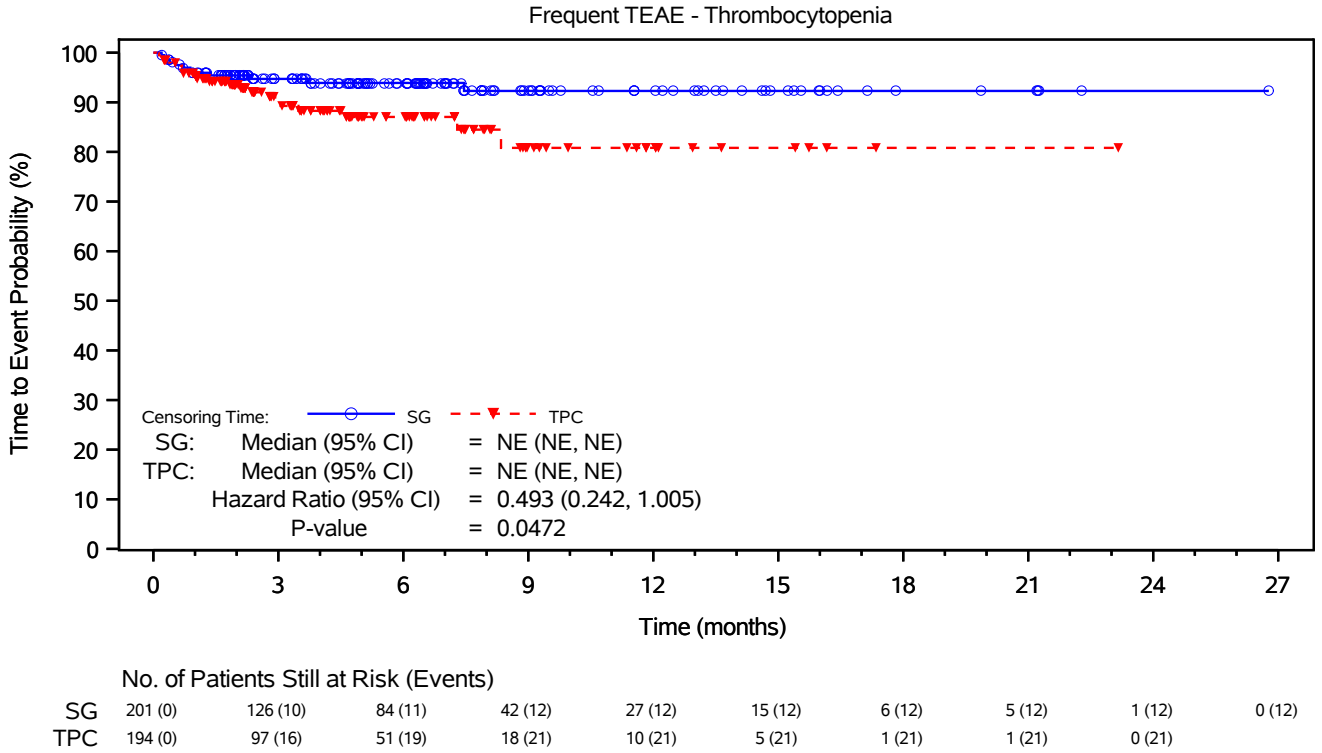

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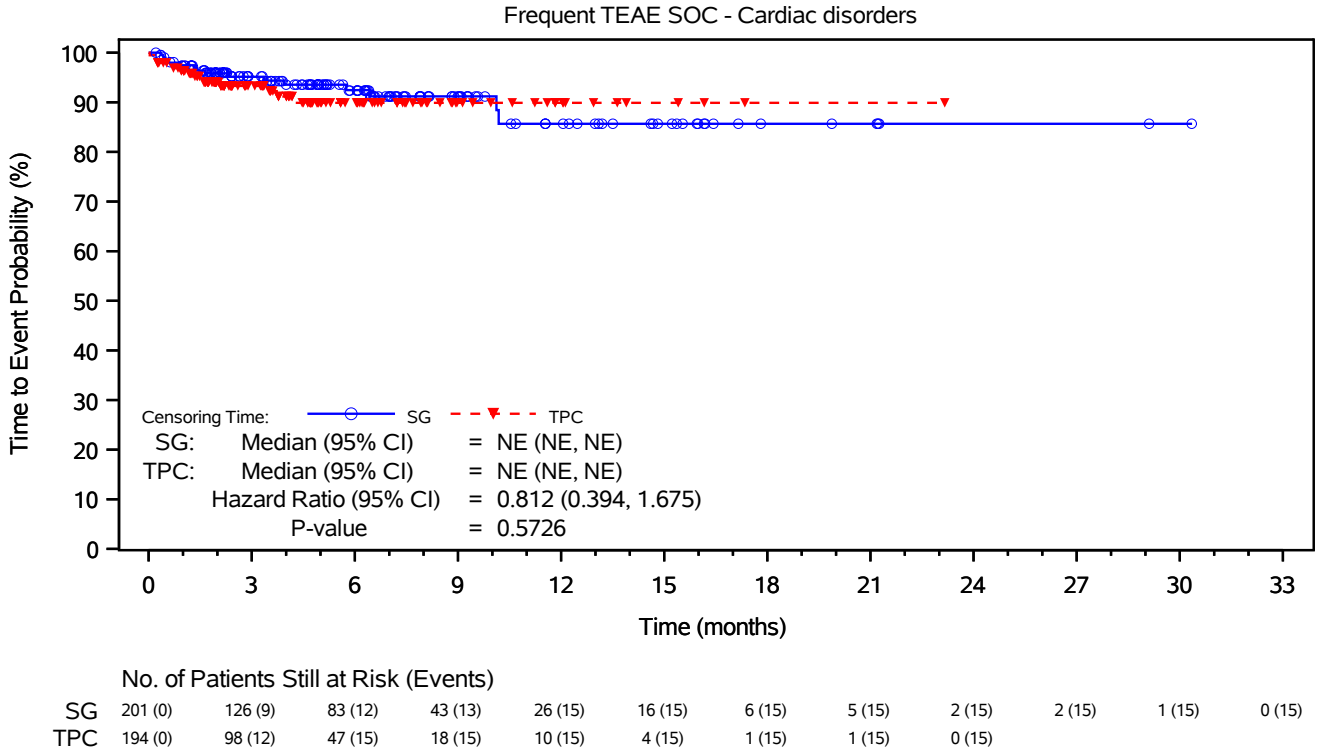
Excluding participants pre-selected to Gemcitabine



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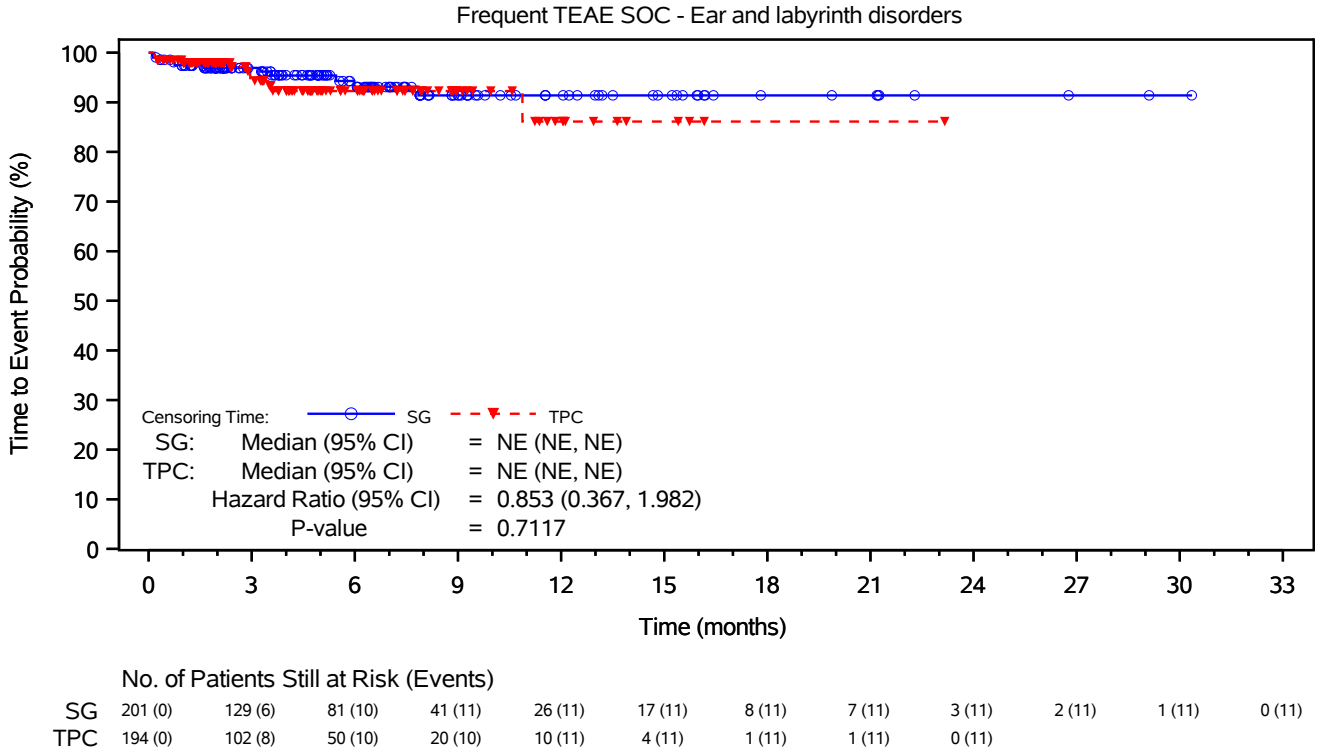

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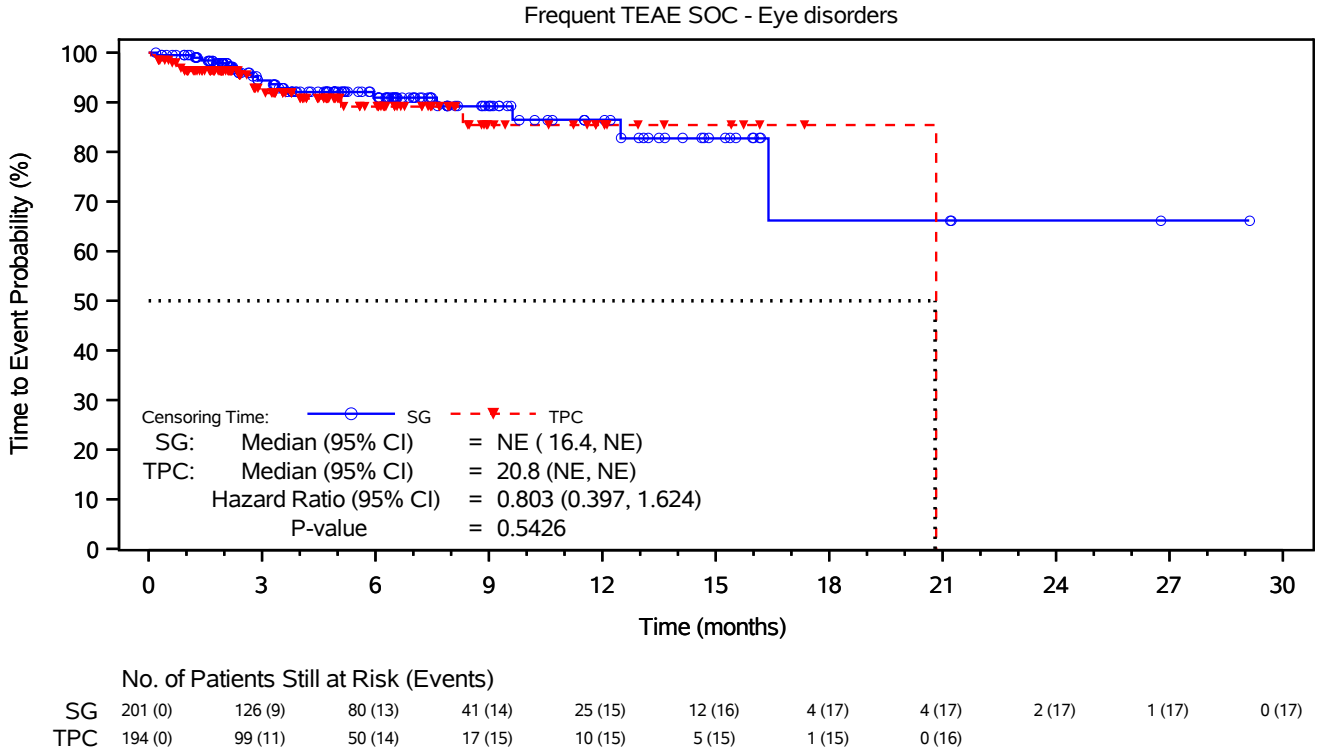

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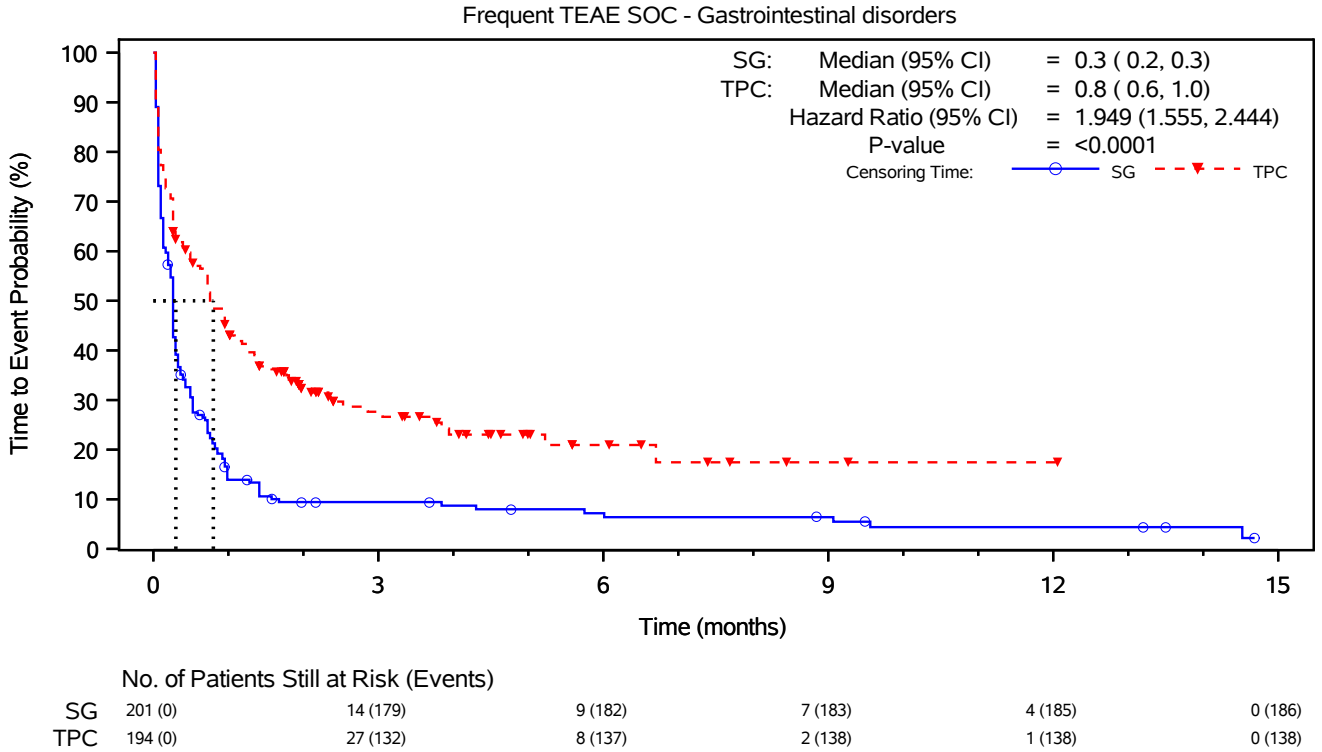

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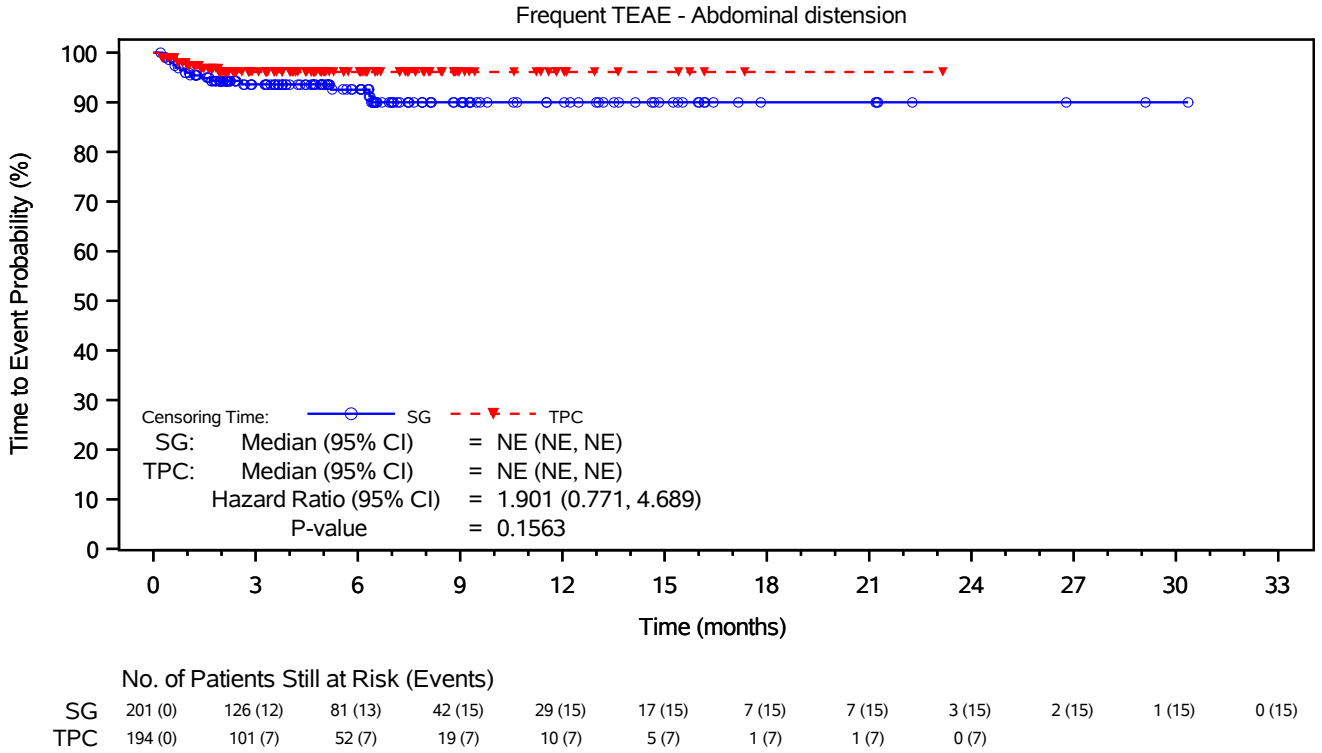

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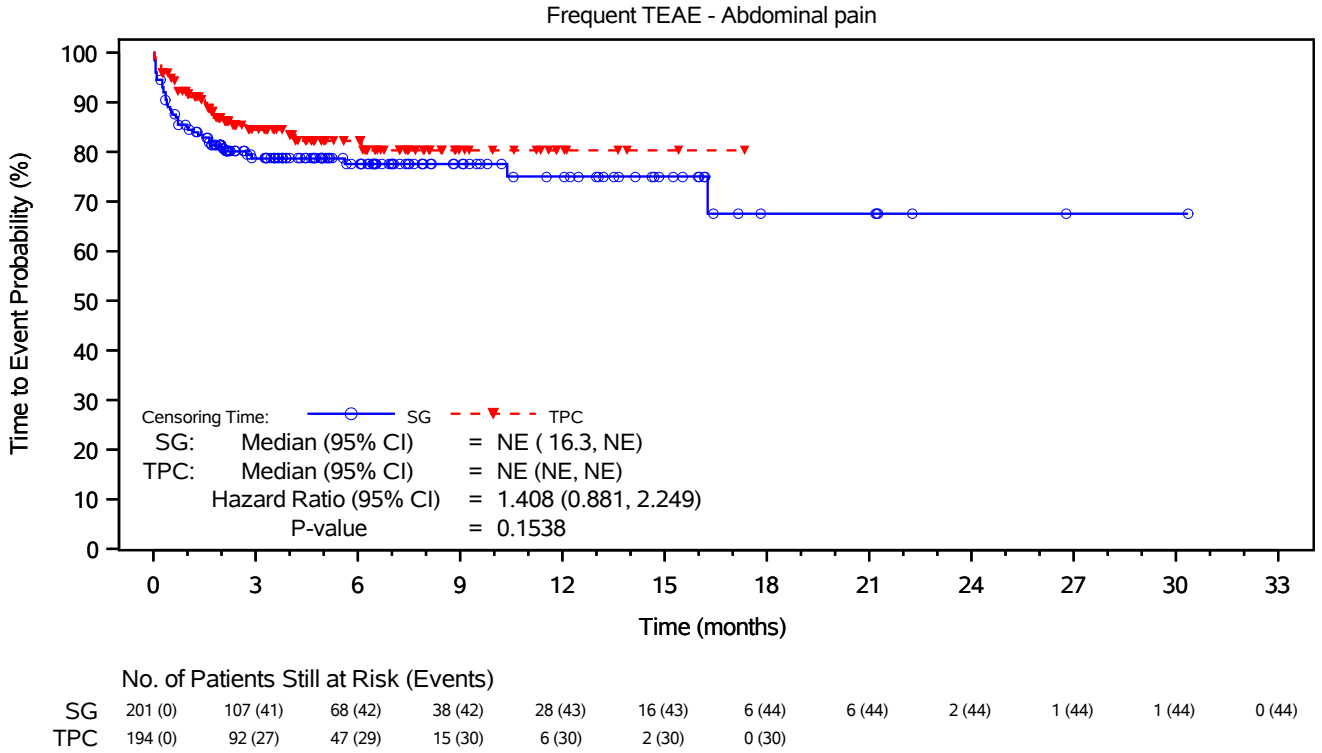

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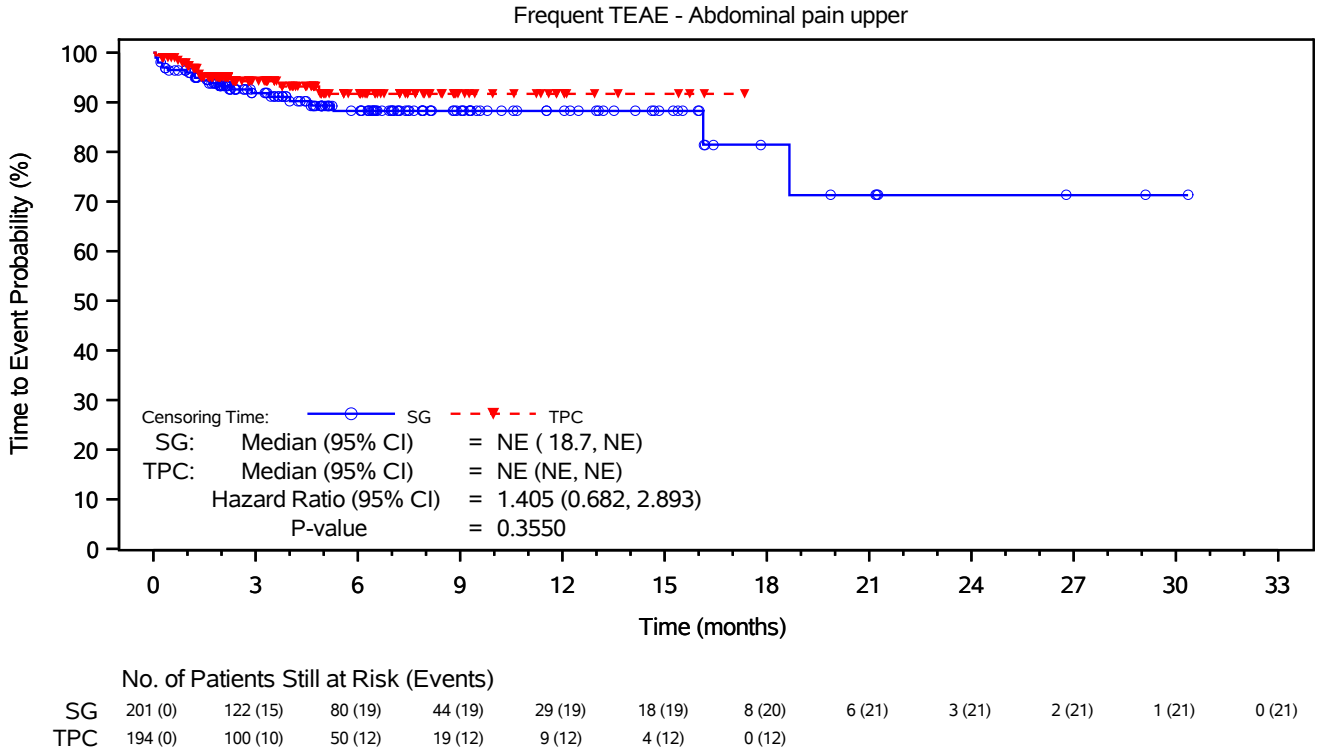

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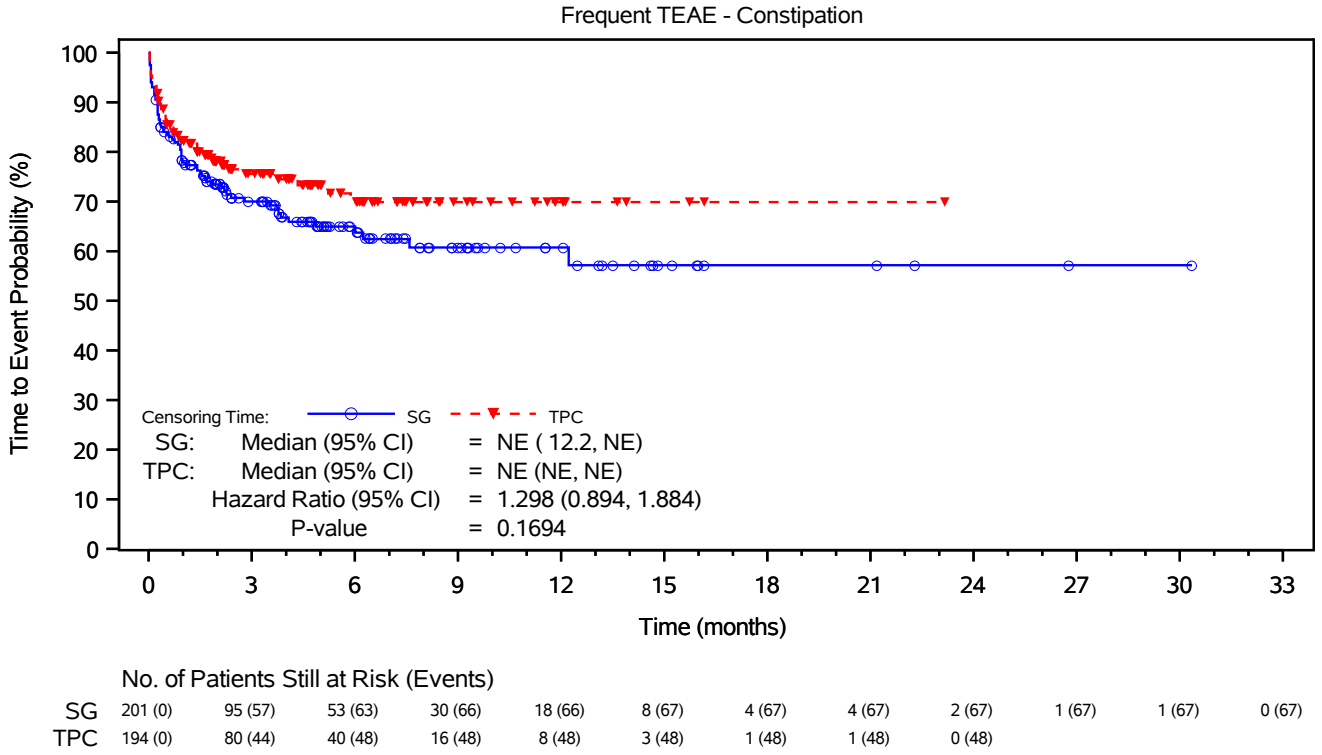

No. of Patients Still at Risk (Events)

SG	201 (0)	95 (57)	53 (63)	30 (66)	18 (66)	8 (67)	4 (67)	4 (67)	2 (67)	1 (67)	1 (67)	0 (67)
TPC	194 (0)	80 (44)	40 (48)	16 (48)	8 (48)	3 (48)	1 (48)	1 (48)	0 (48)			

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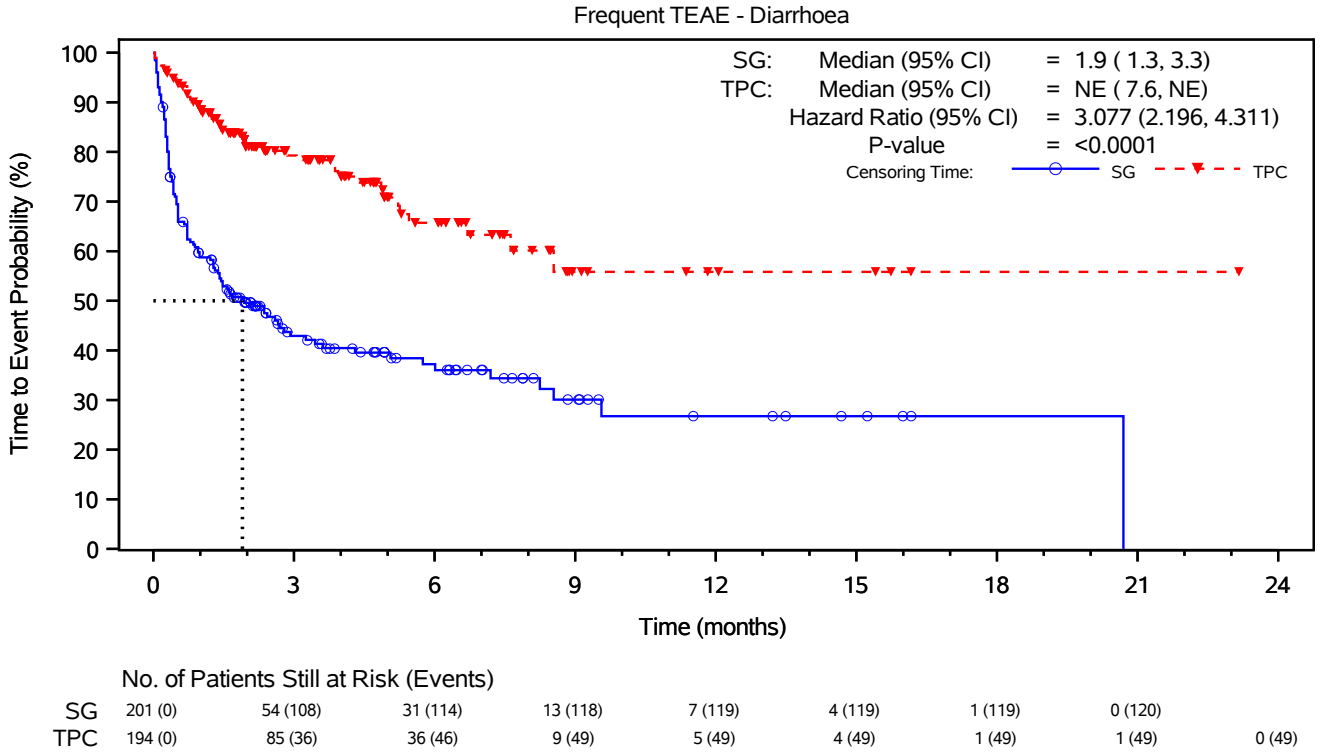

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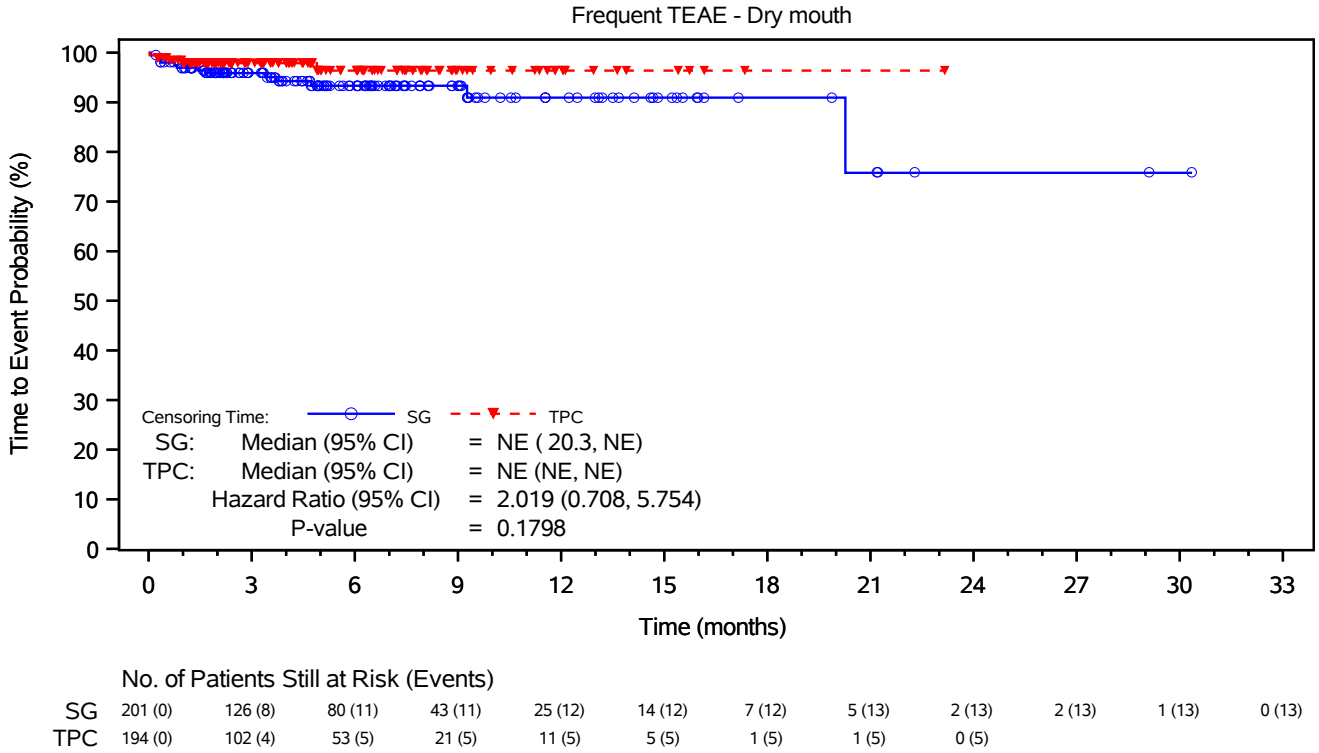

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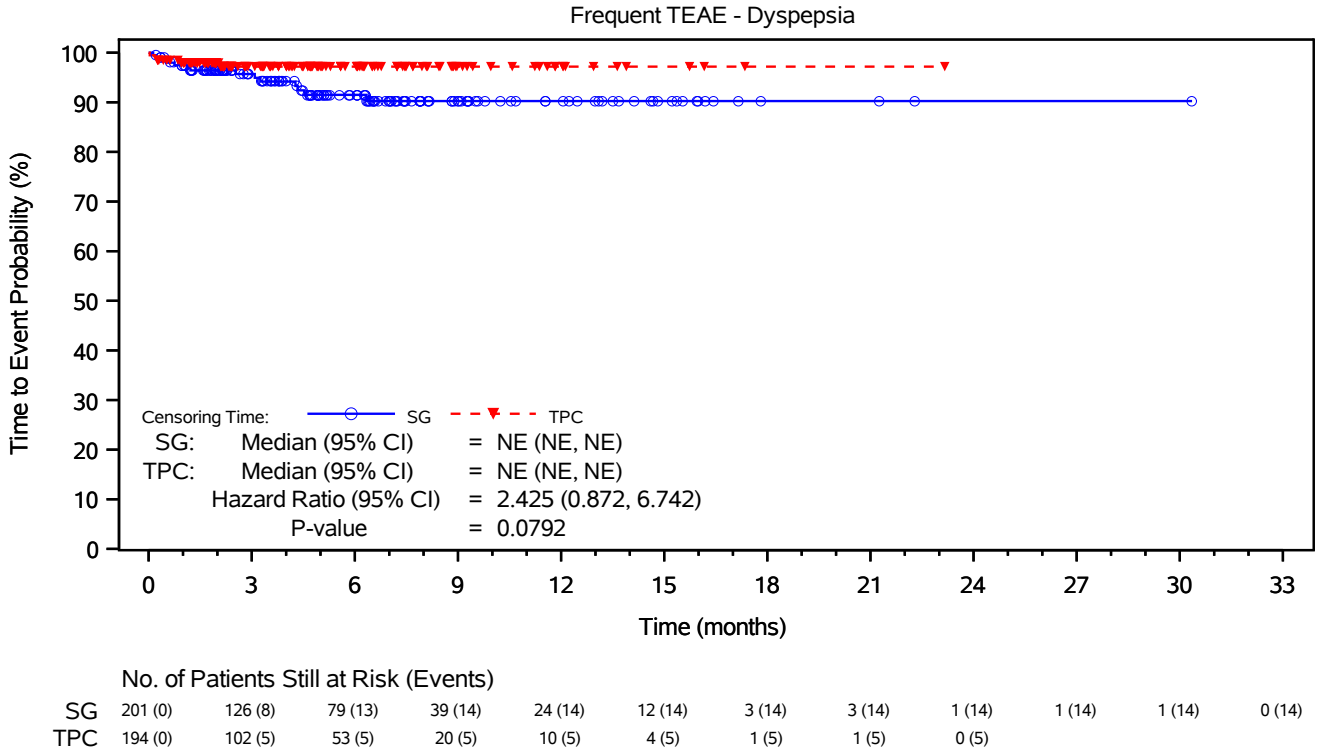

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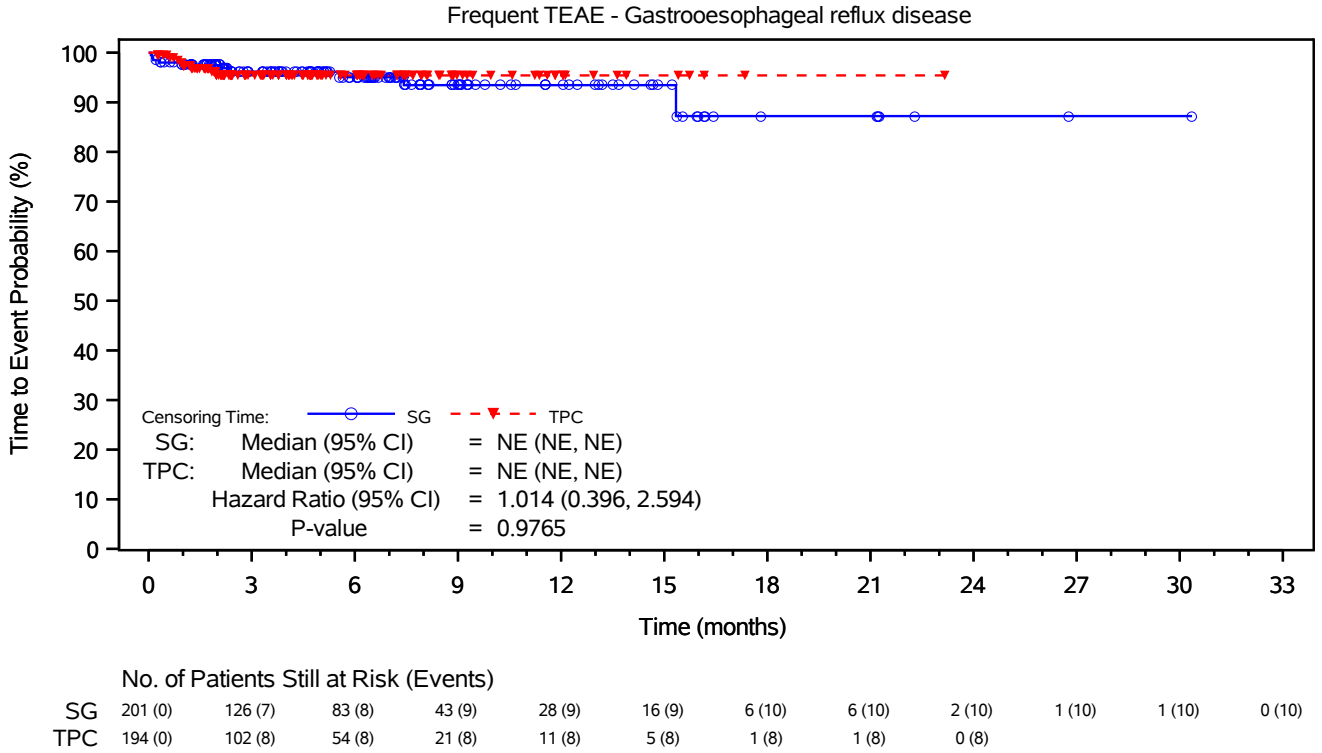

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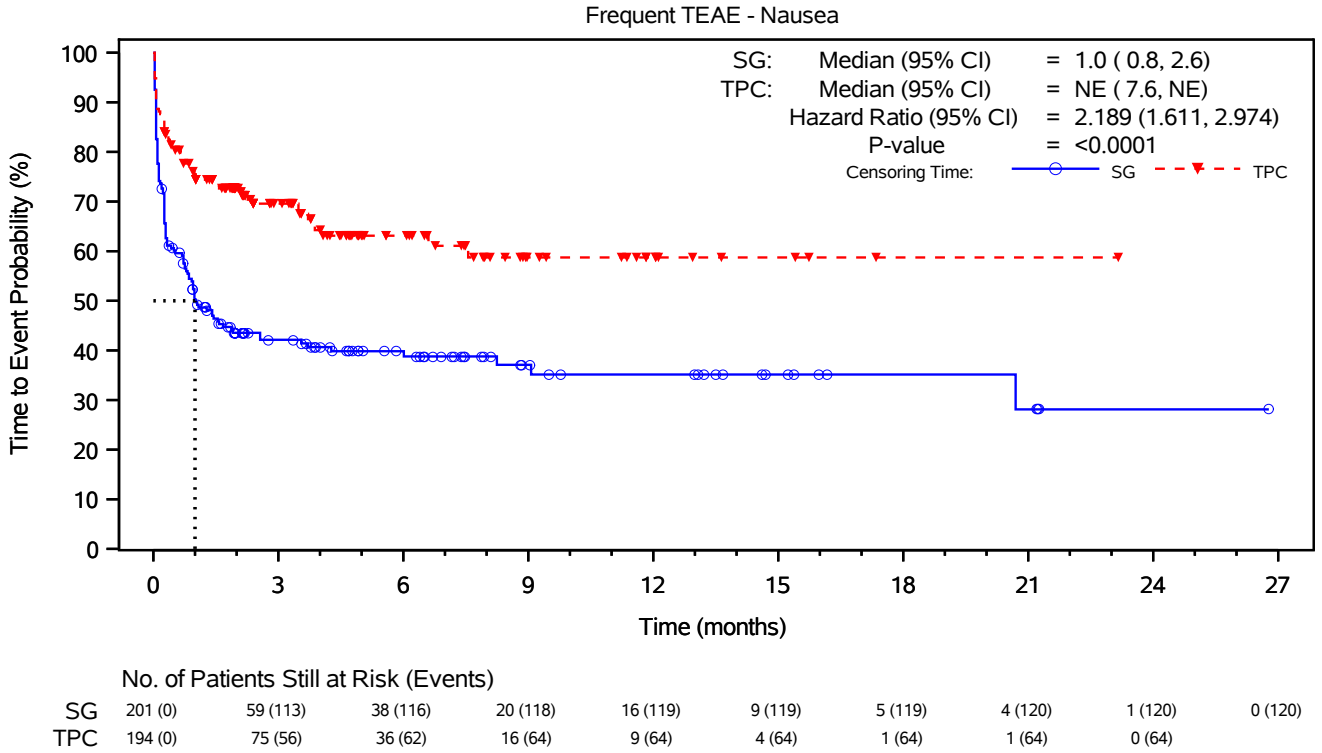
Excluding participants pre-selected to Gemcitabine



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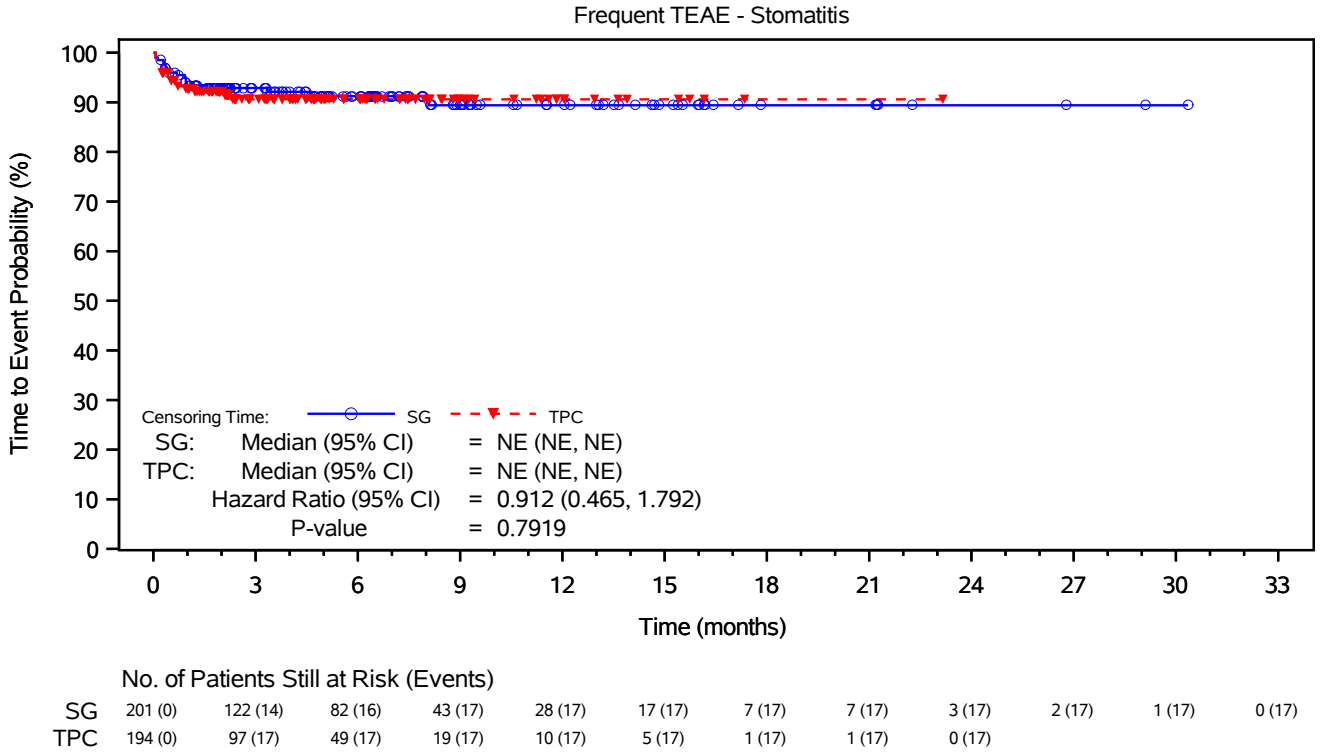

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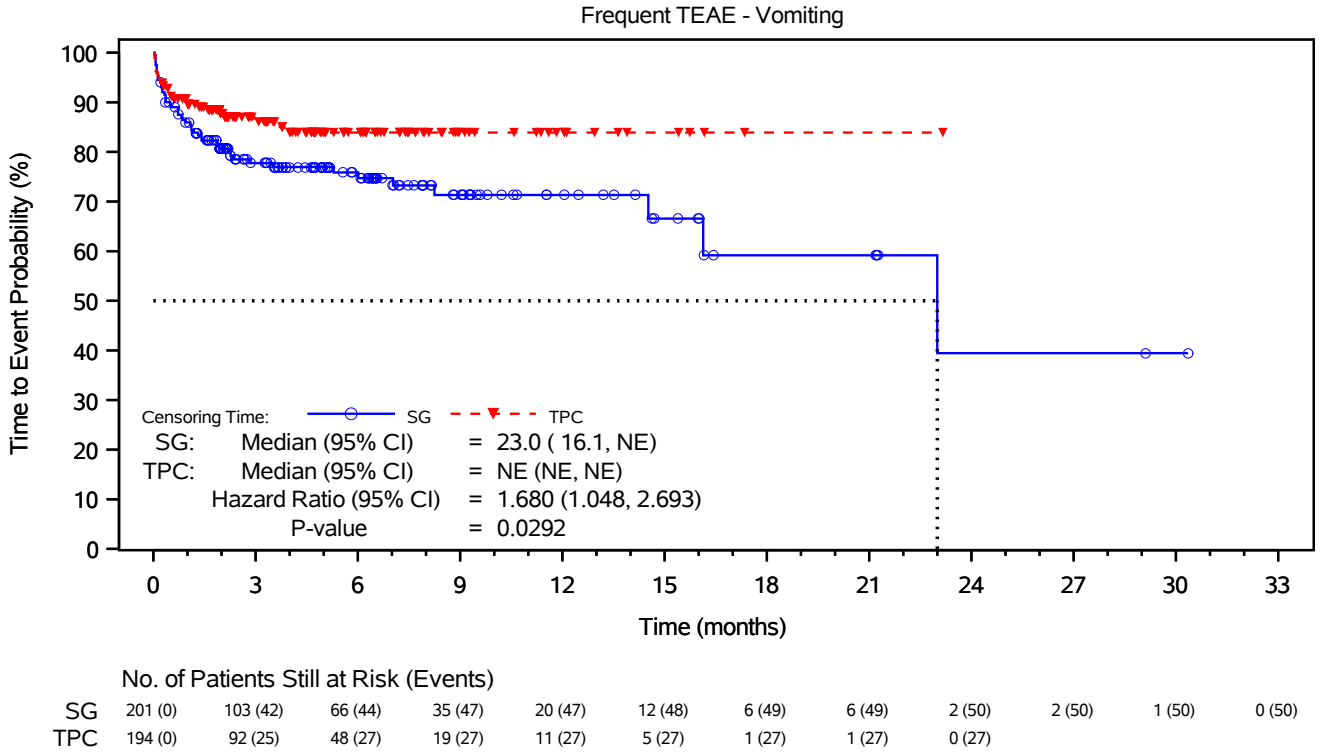

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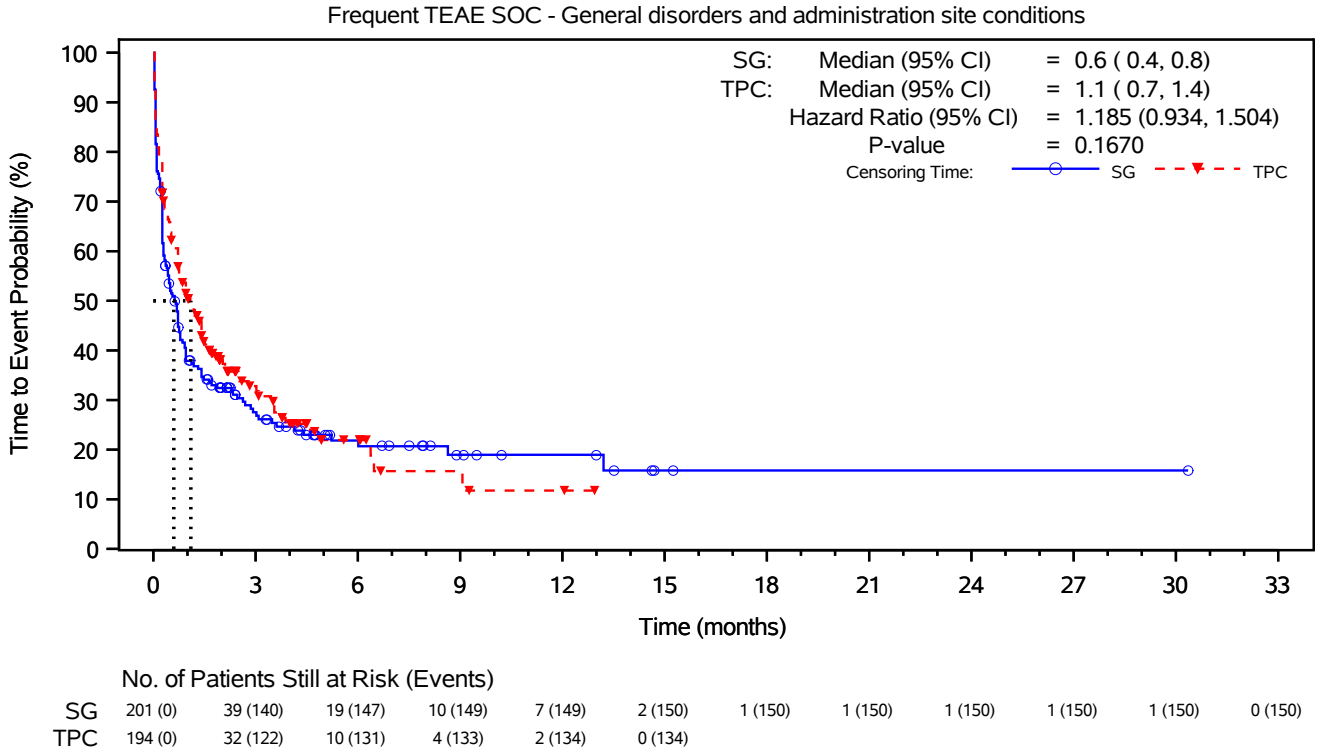

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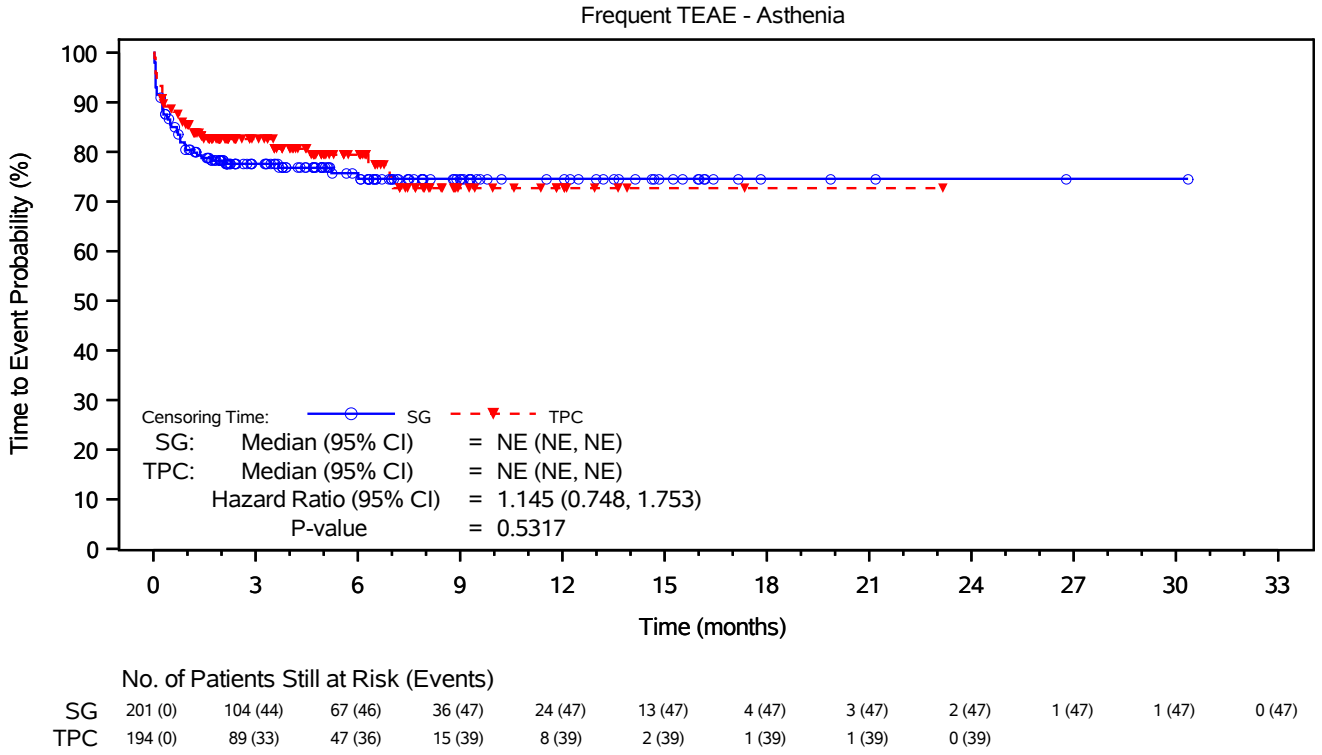

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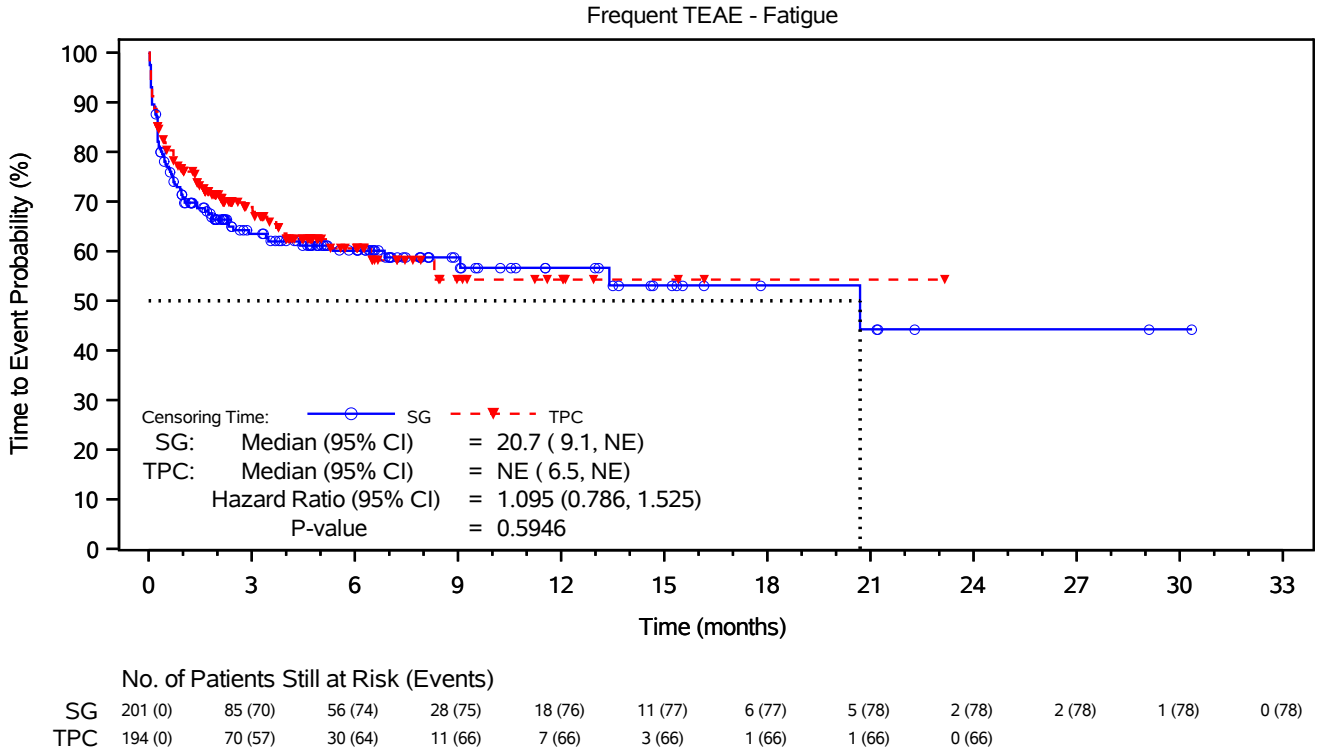

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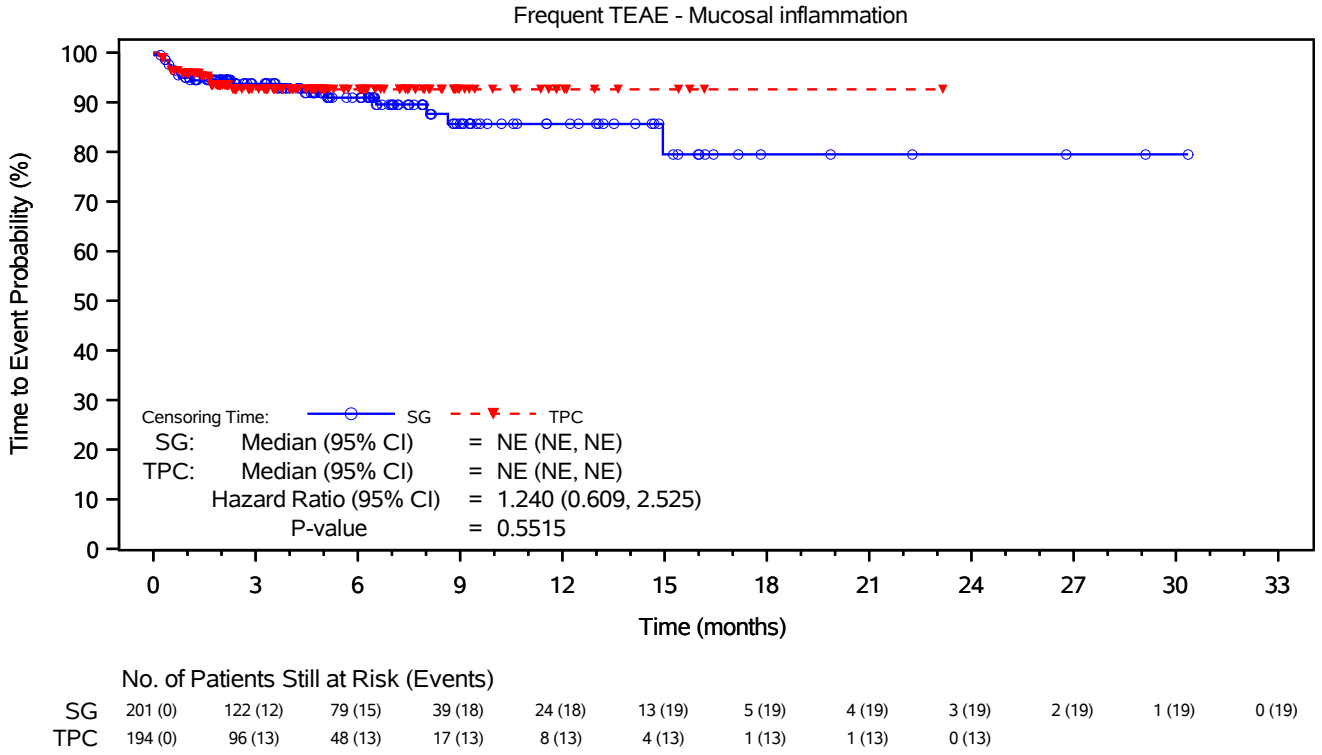

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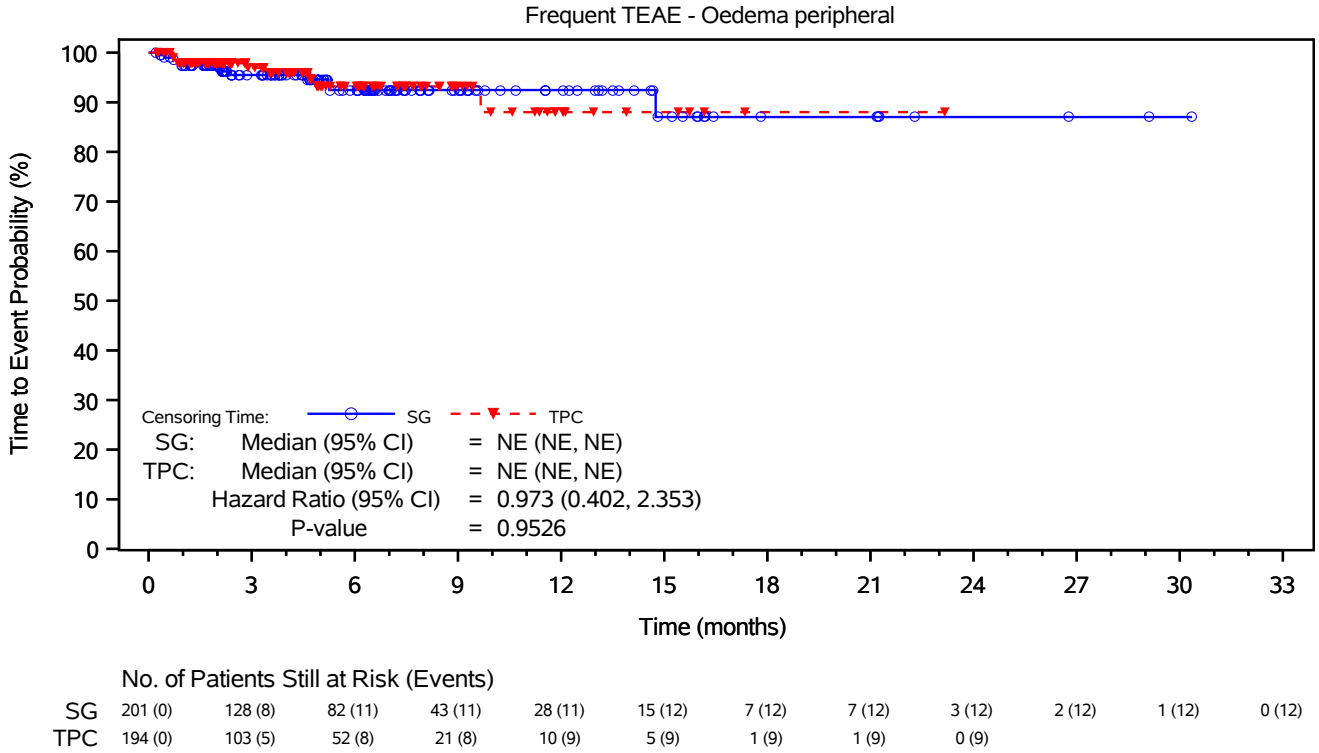

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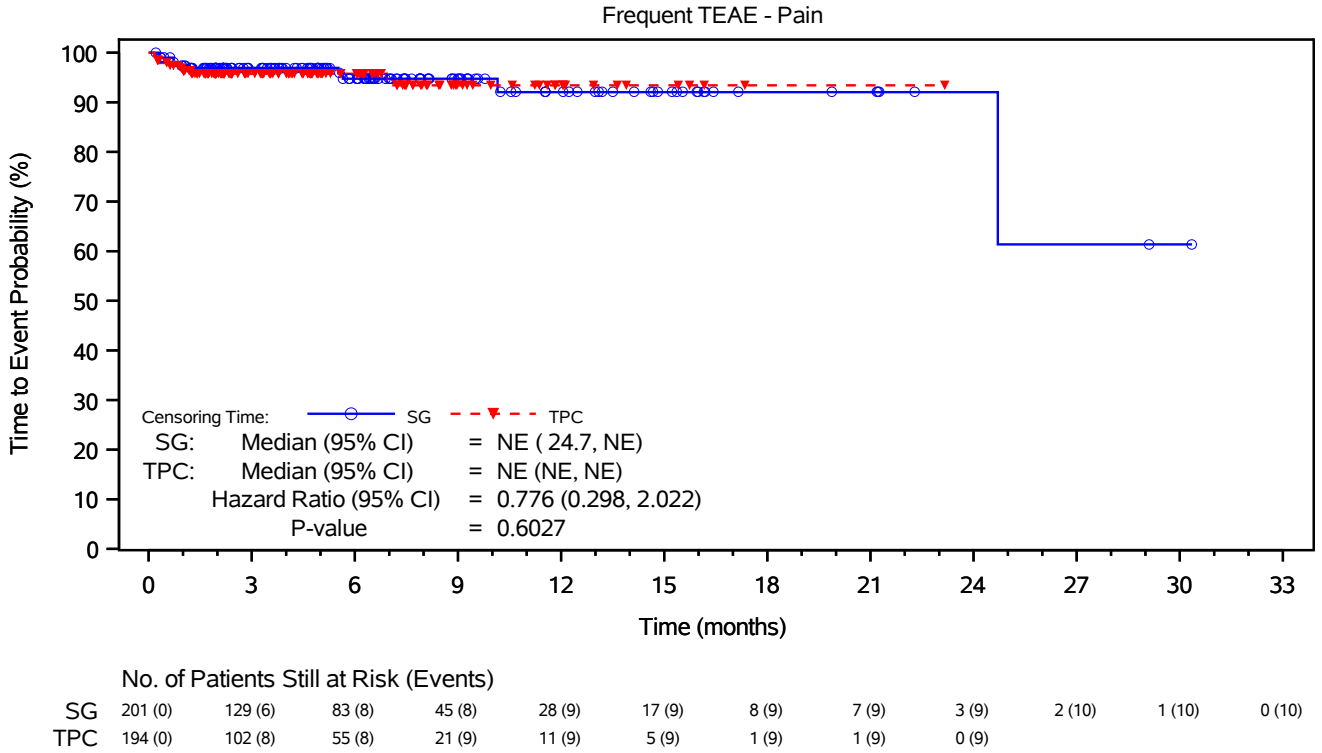

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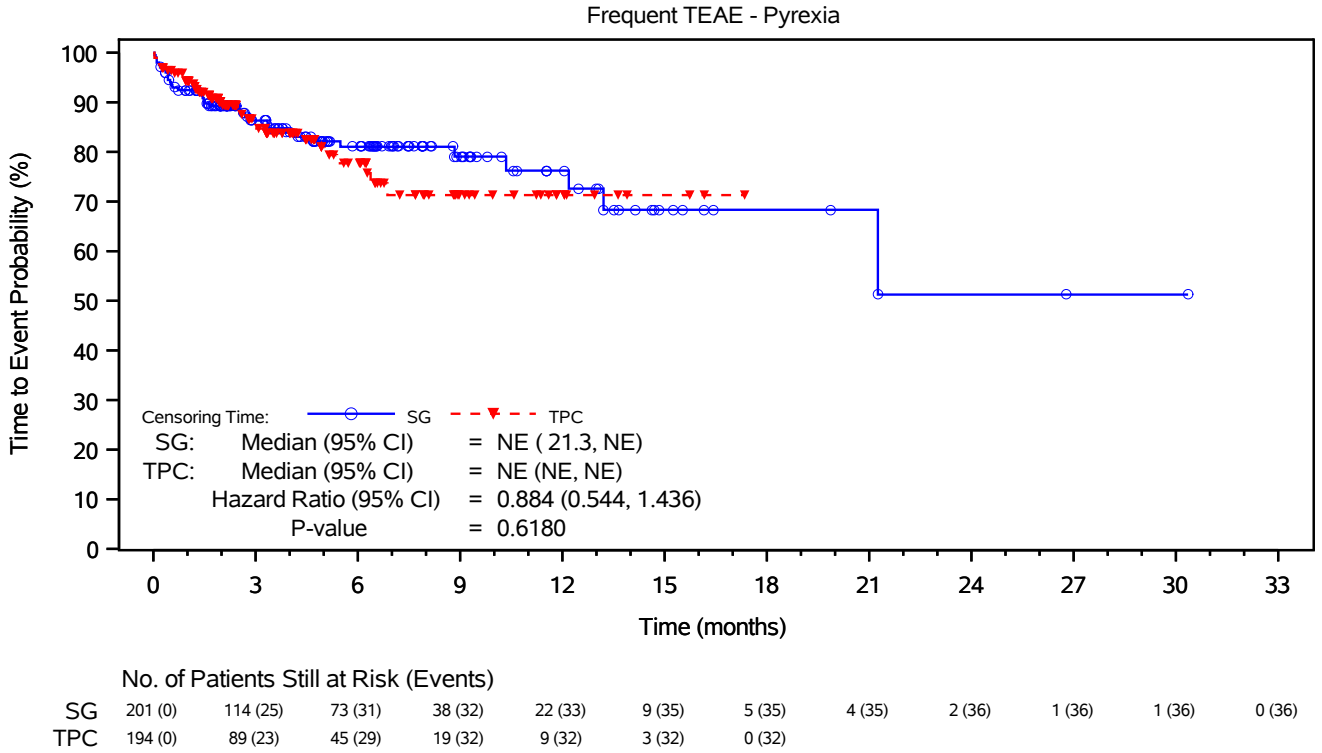

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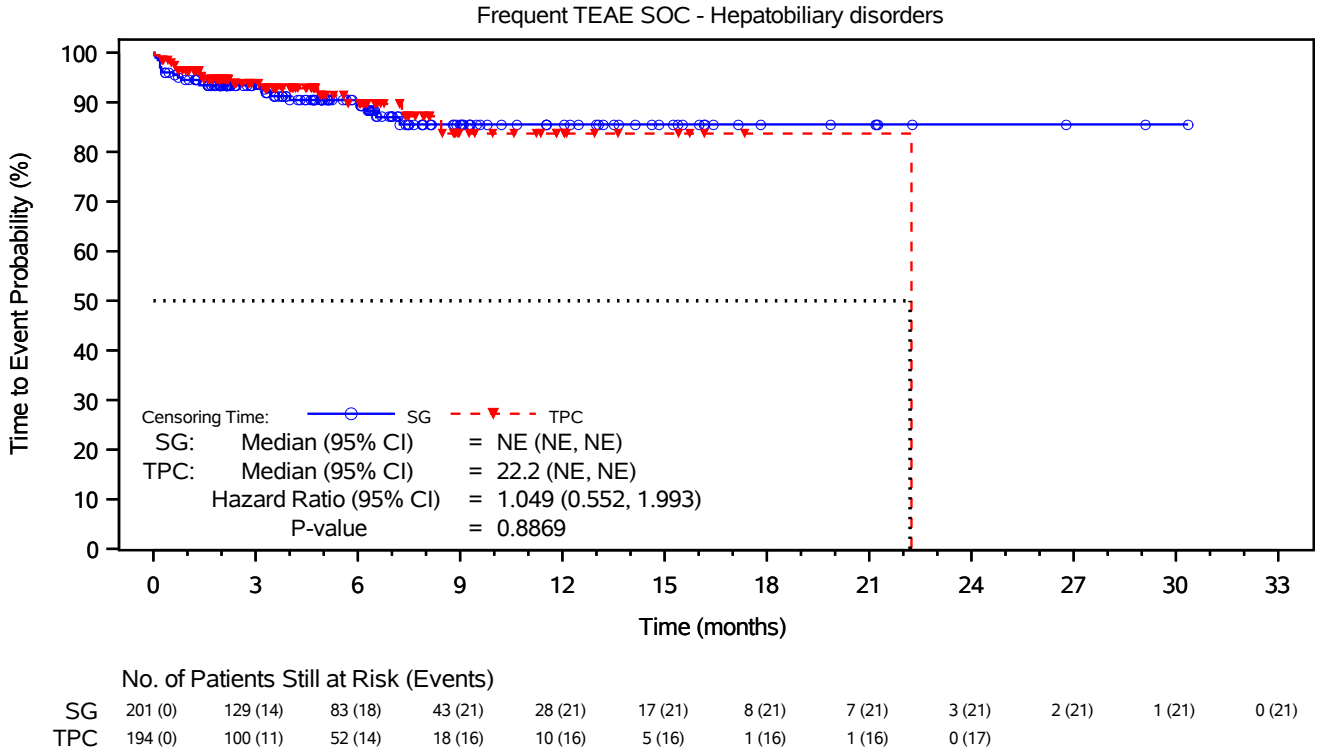

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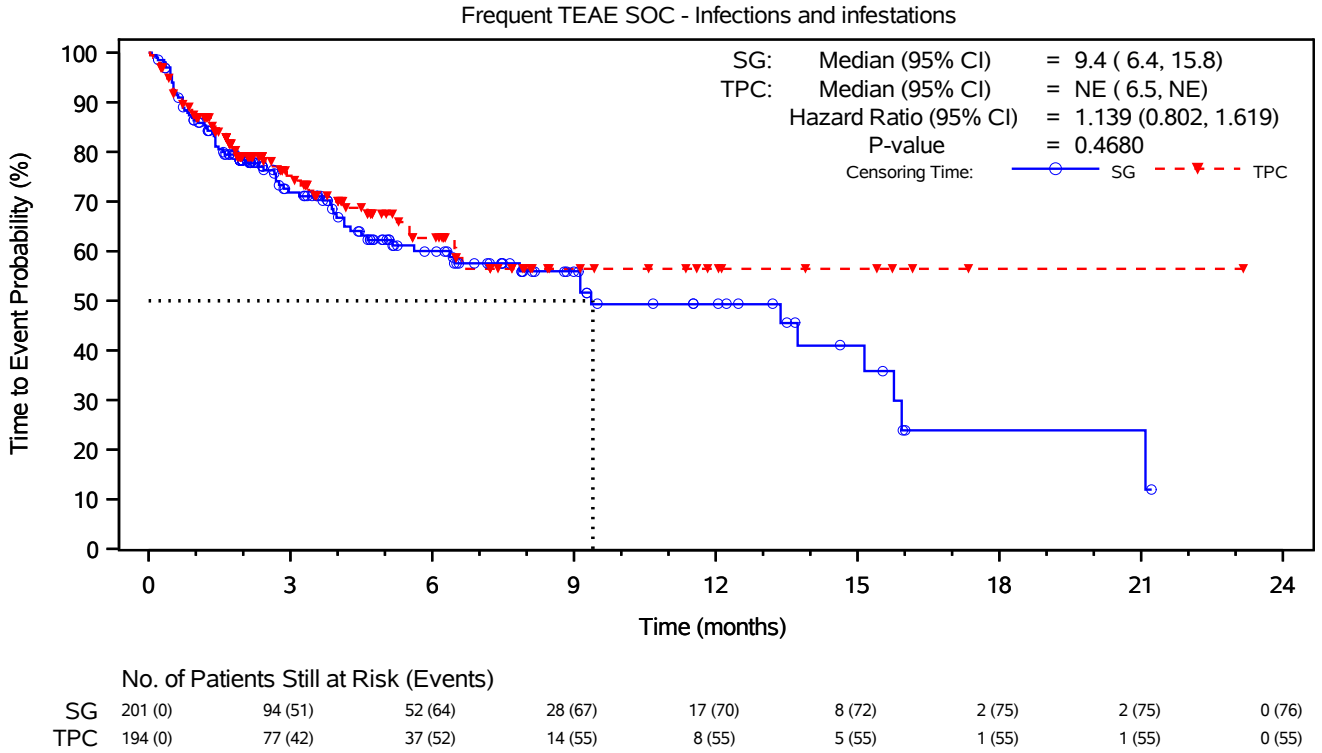

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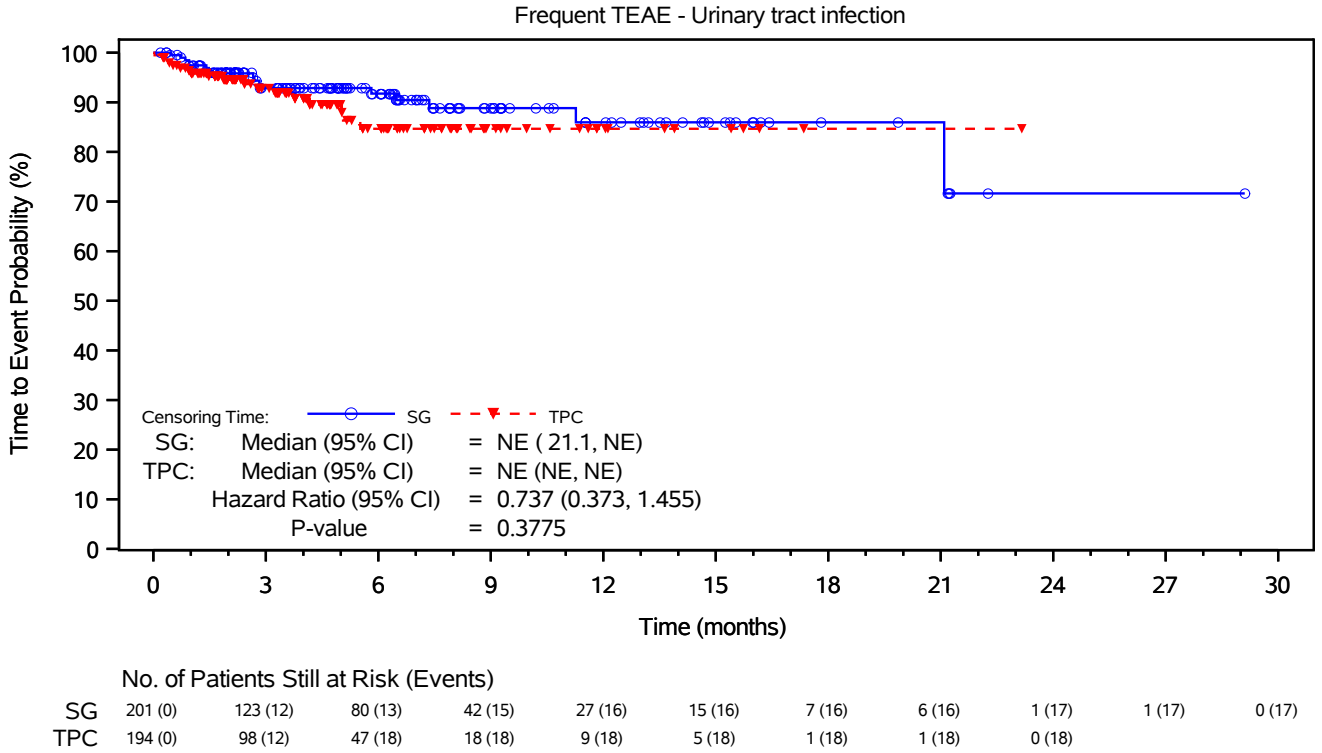

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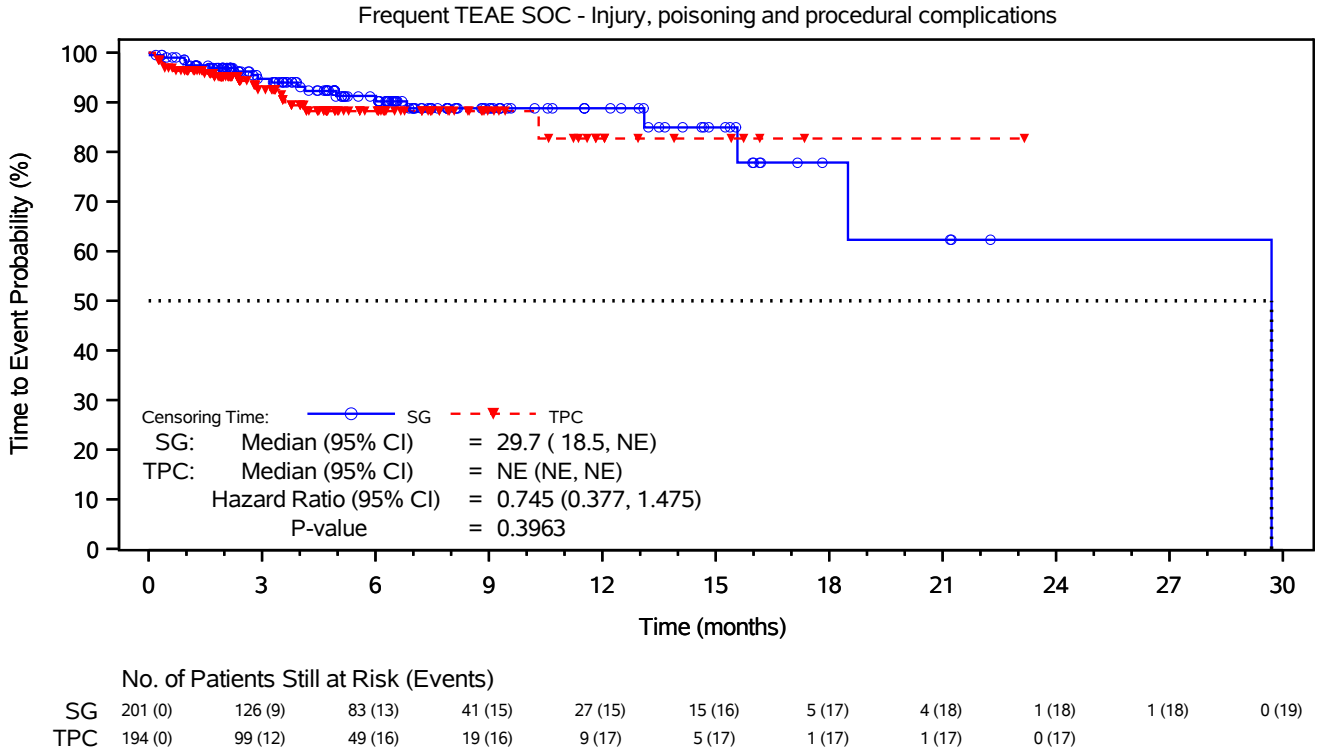

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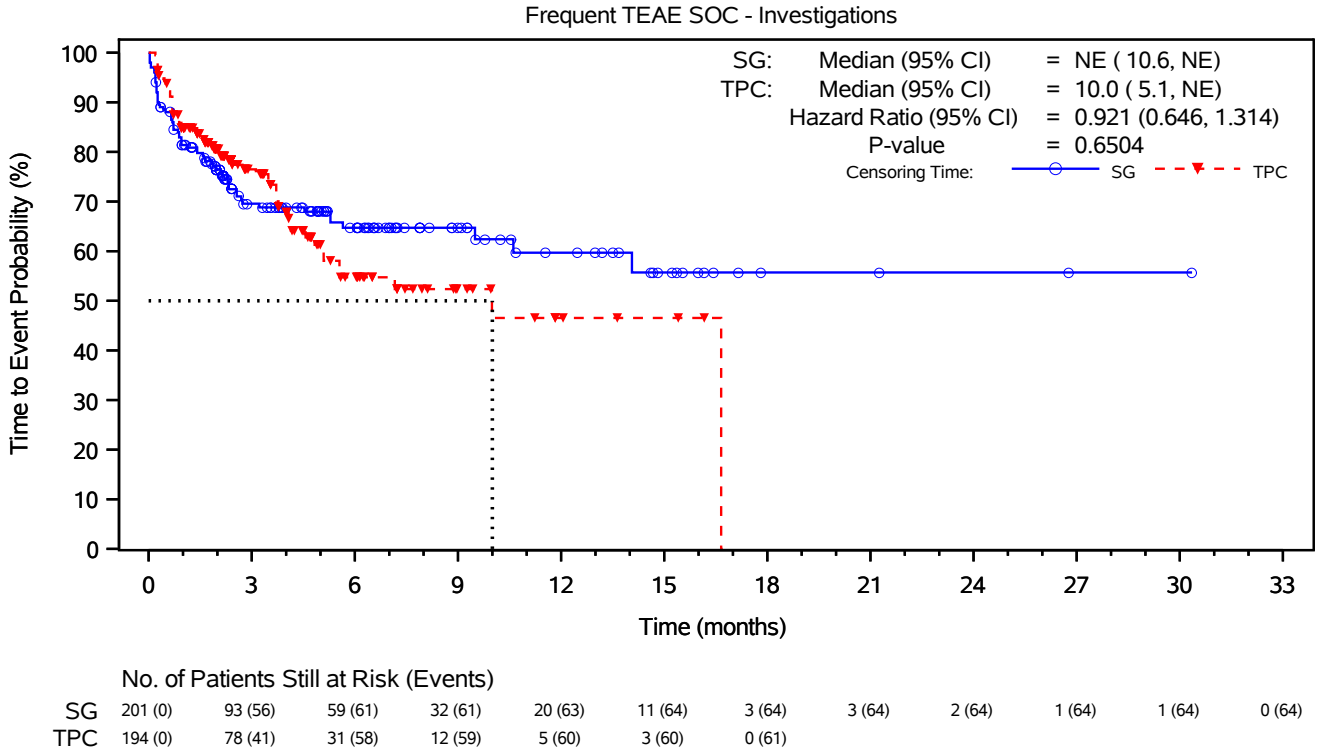

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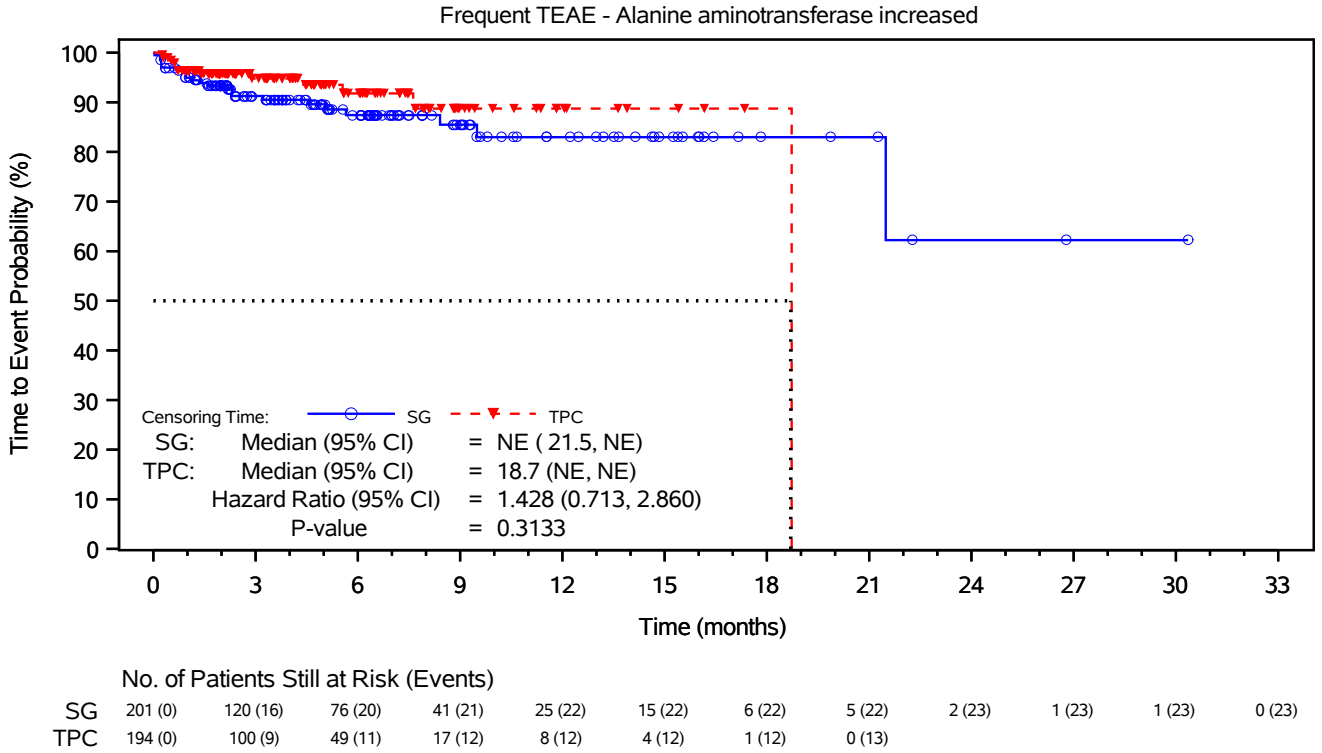

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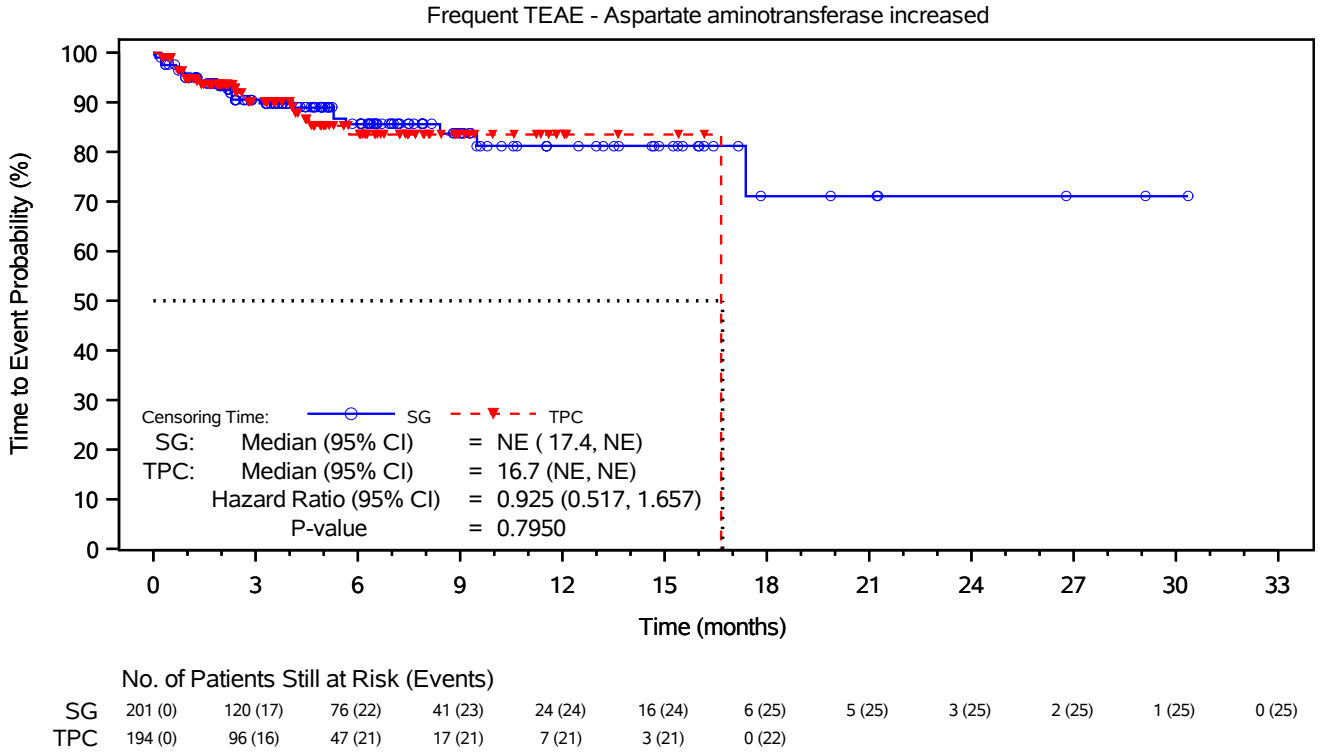

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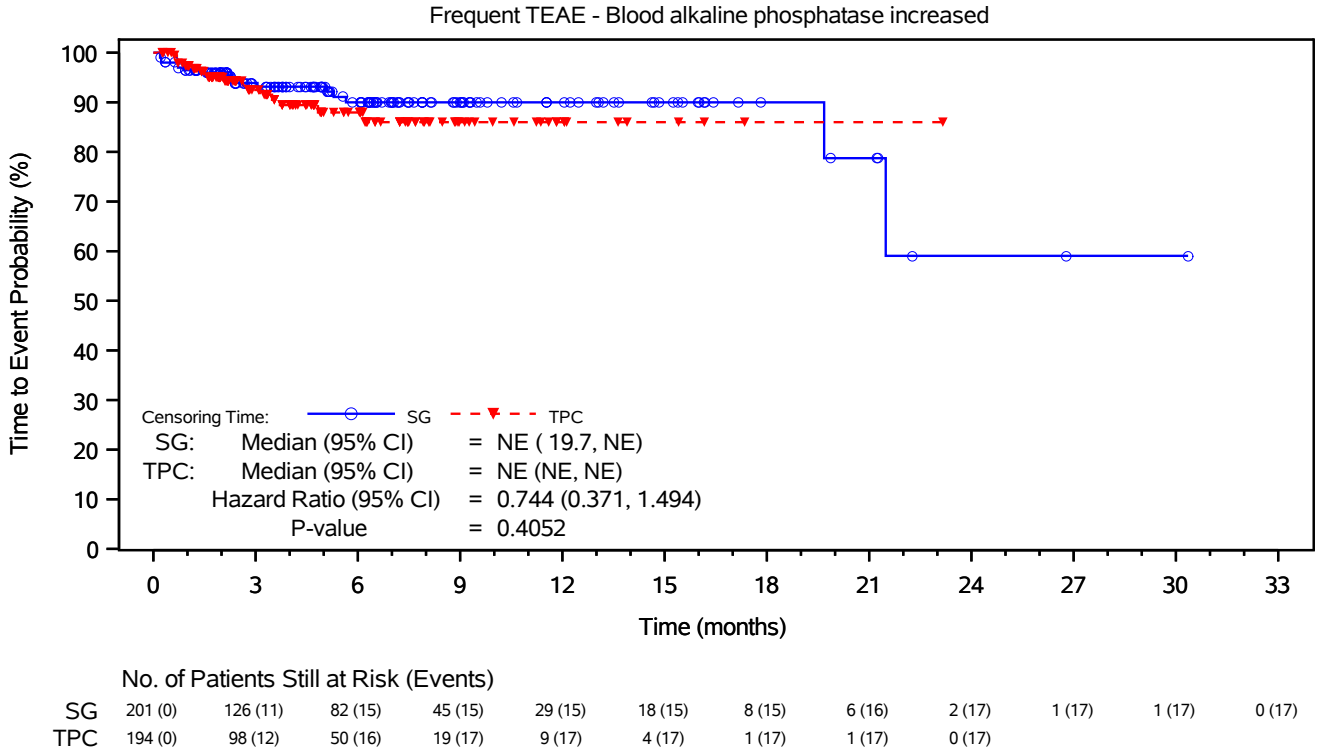

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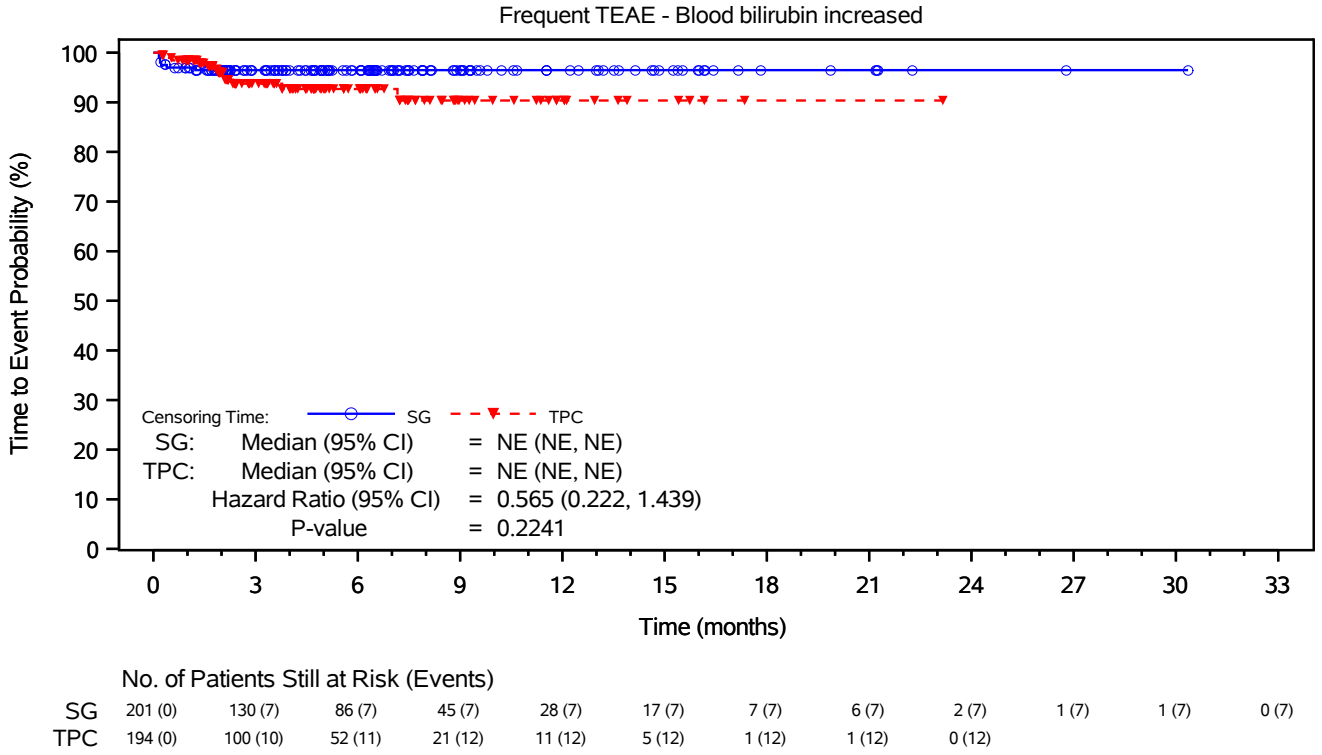

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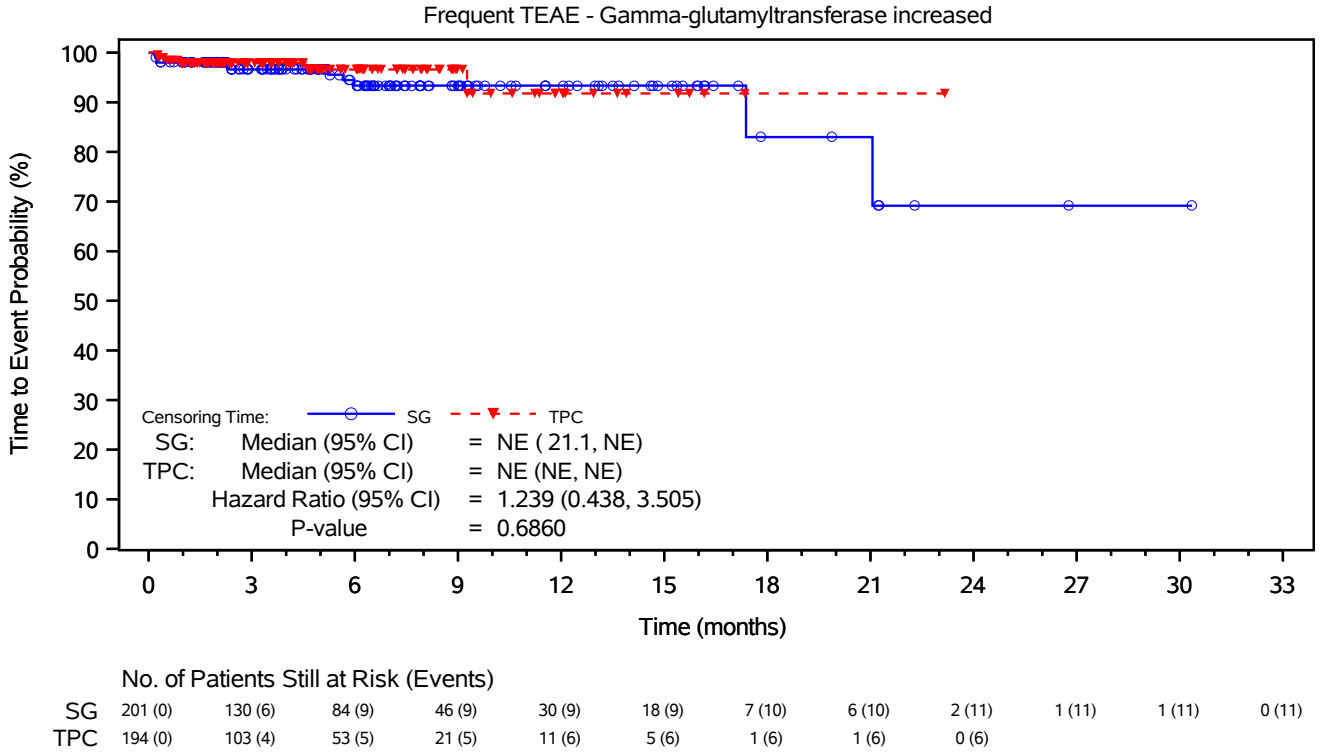

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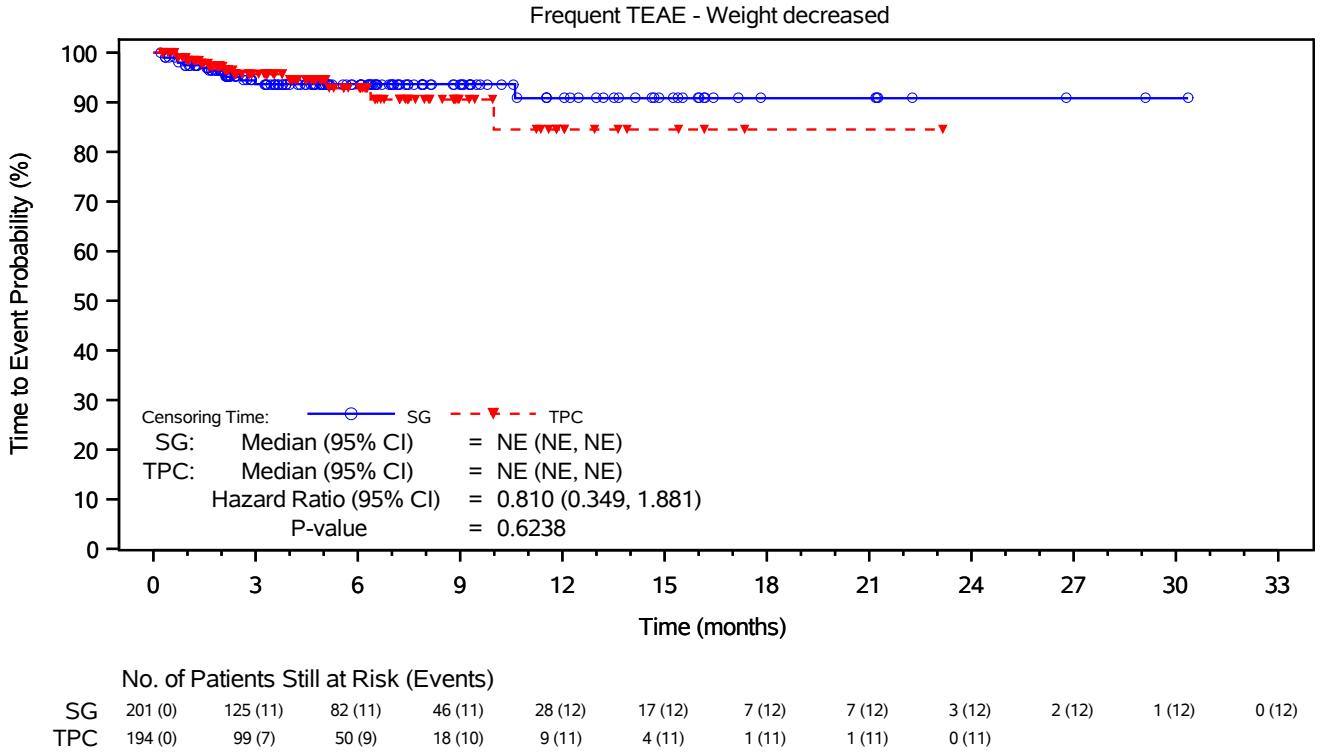

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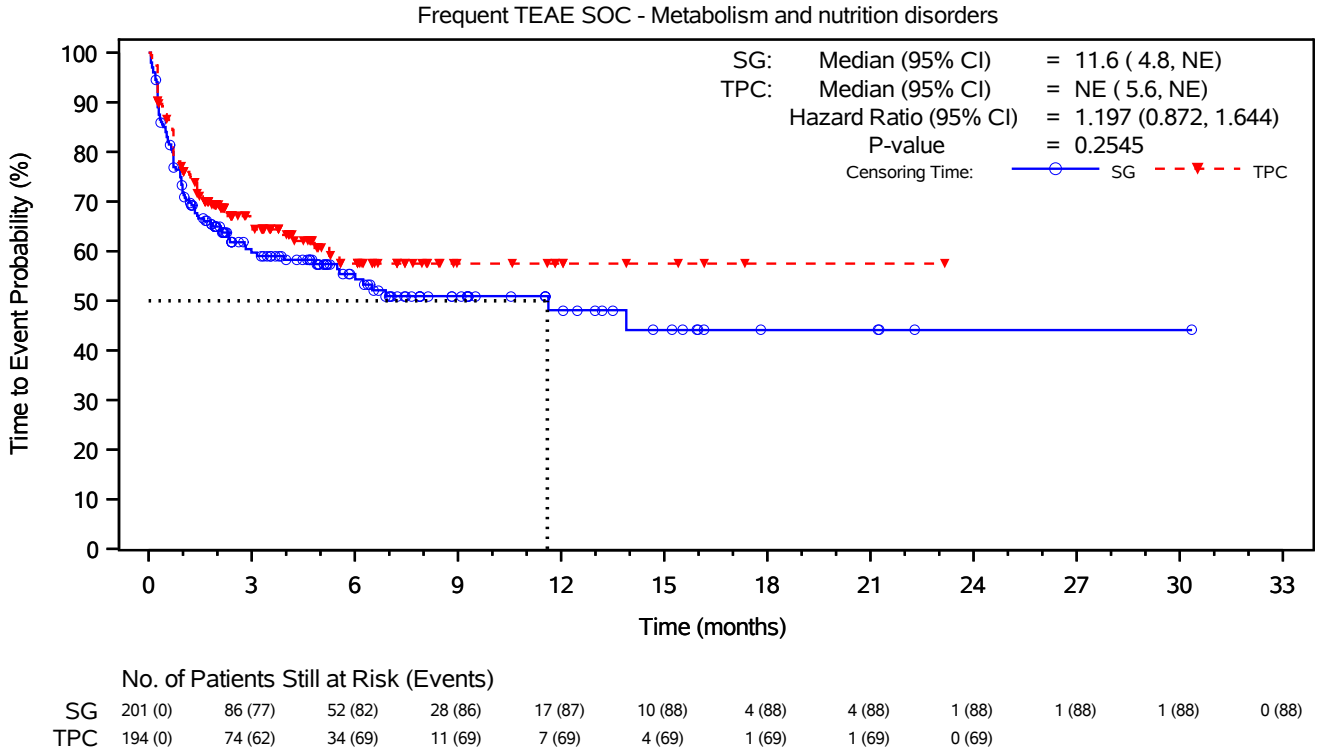
Figure 15.11.7.1: KM Plot for Time to the First Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



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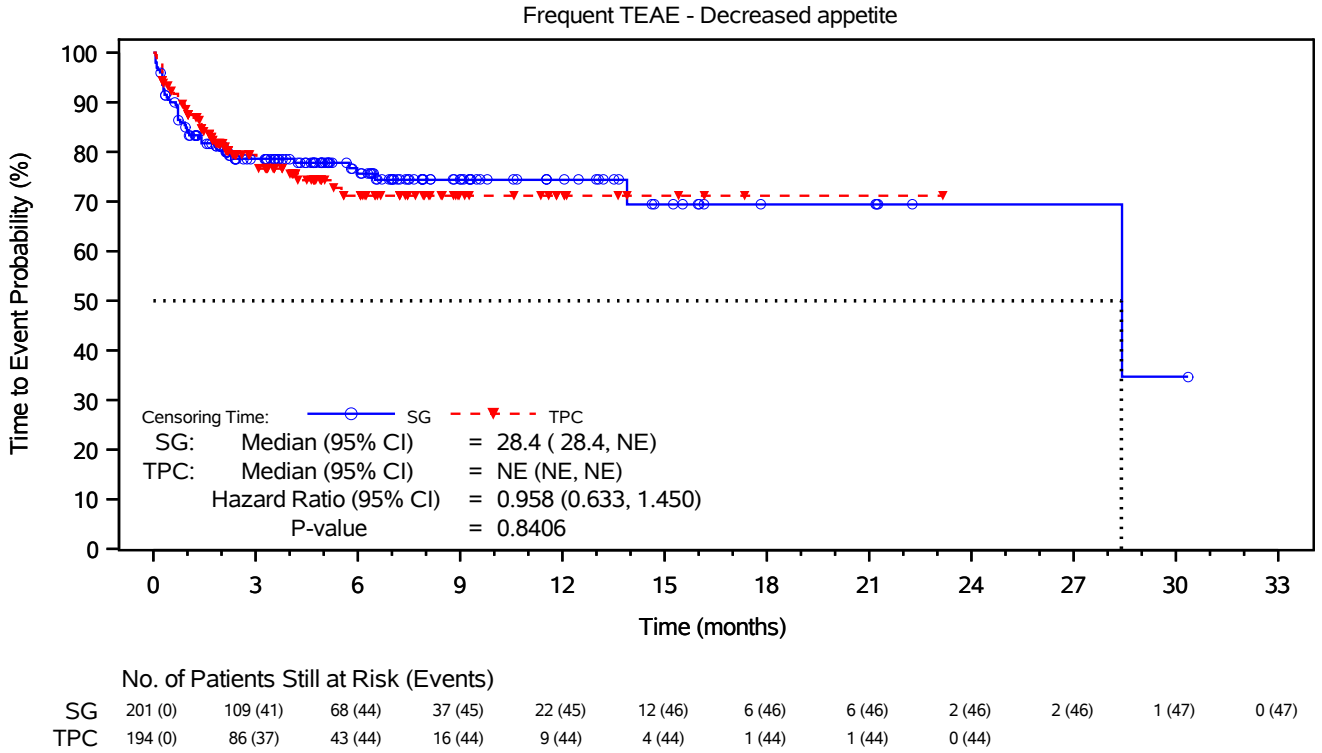

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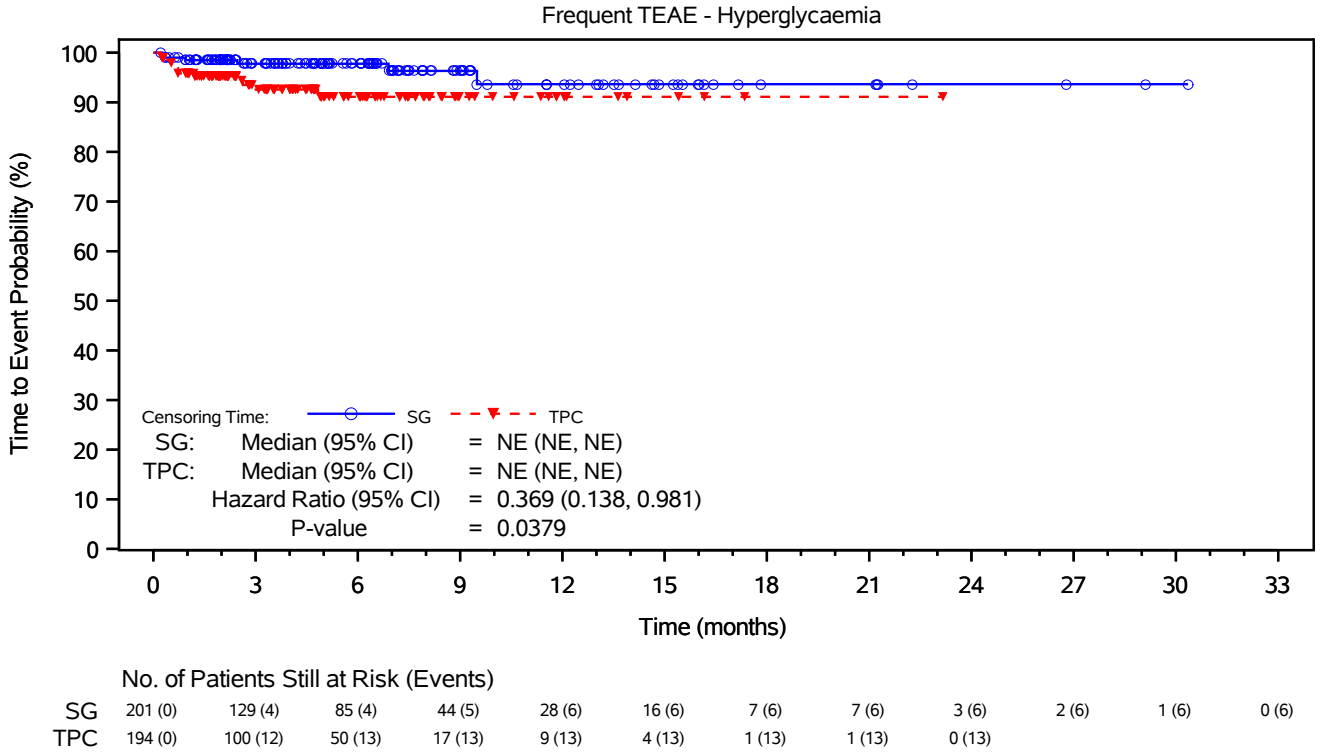

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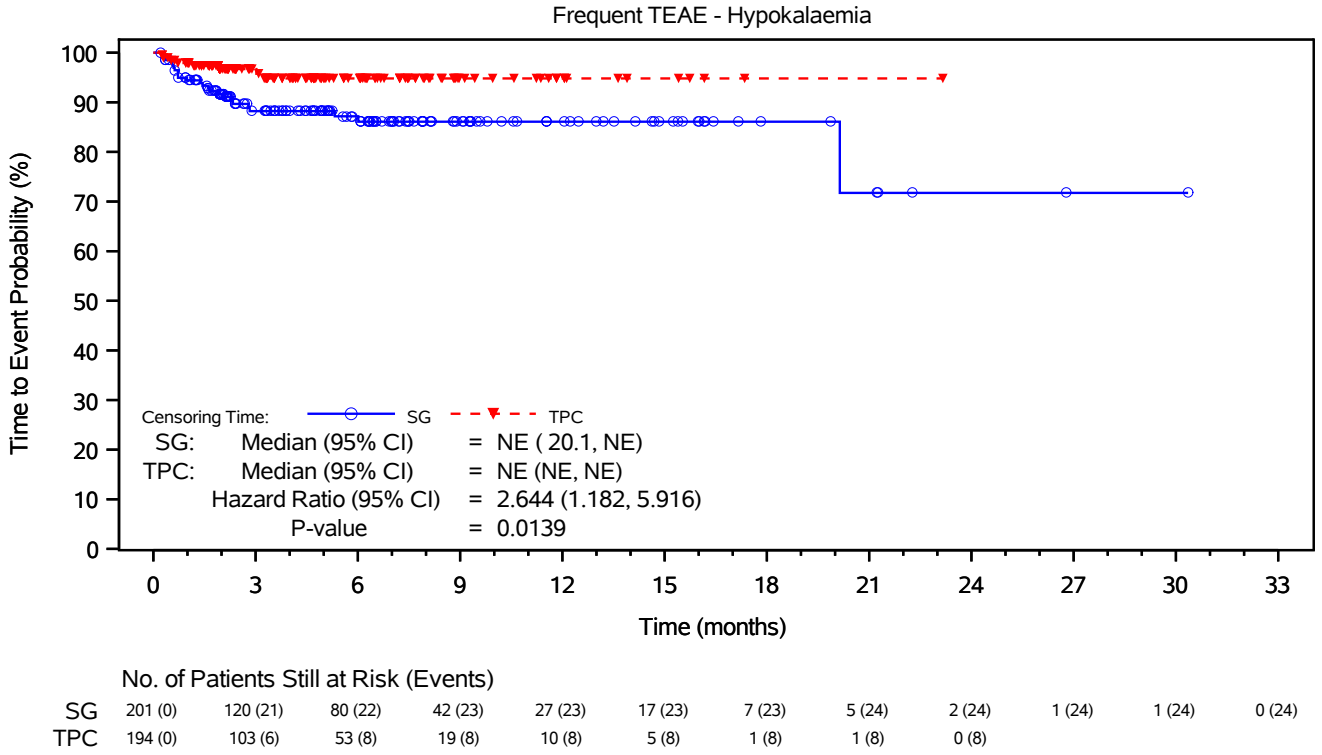

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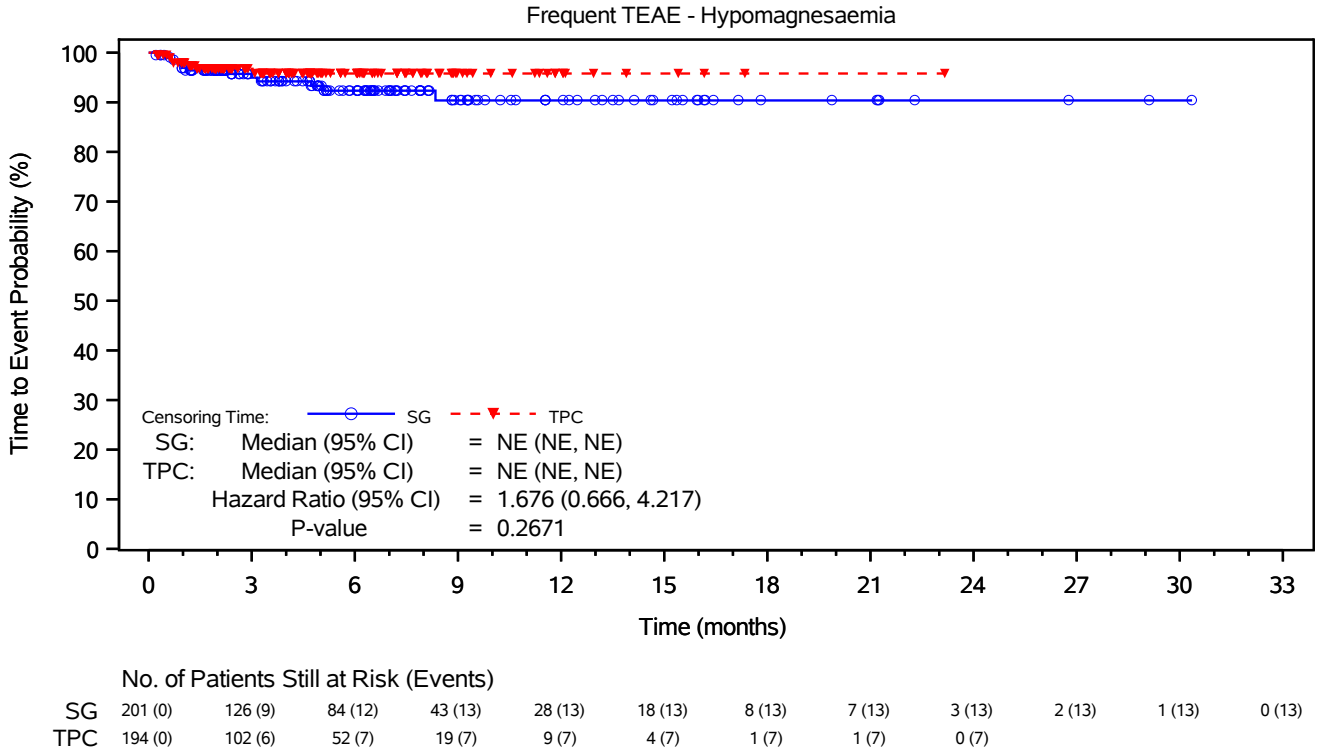

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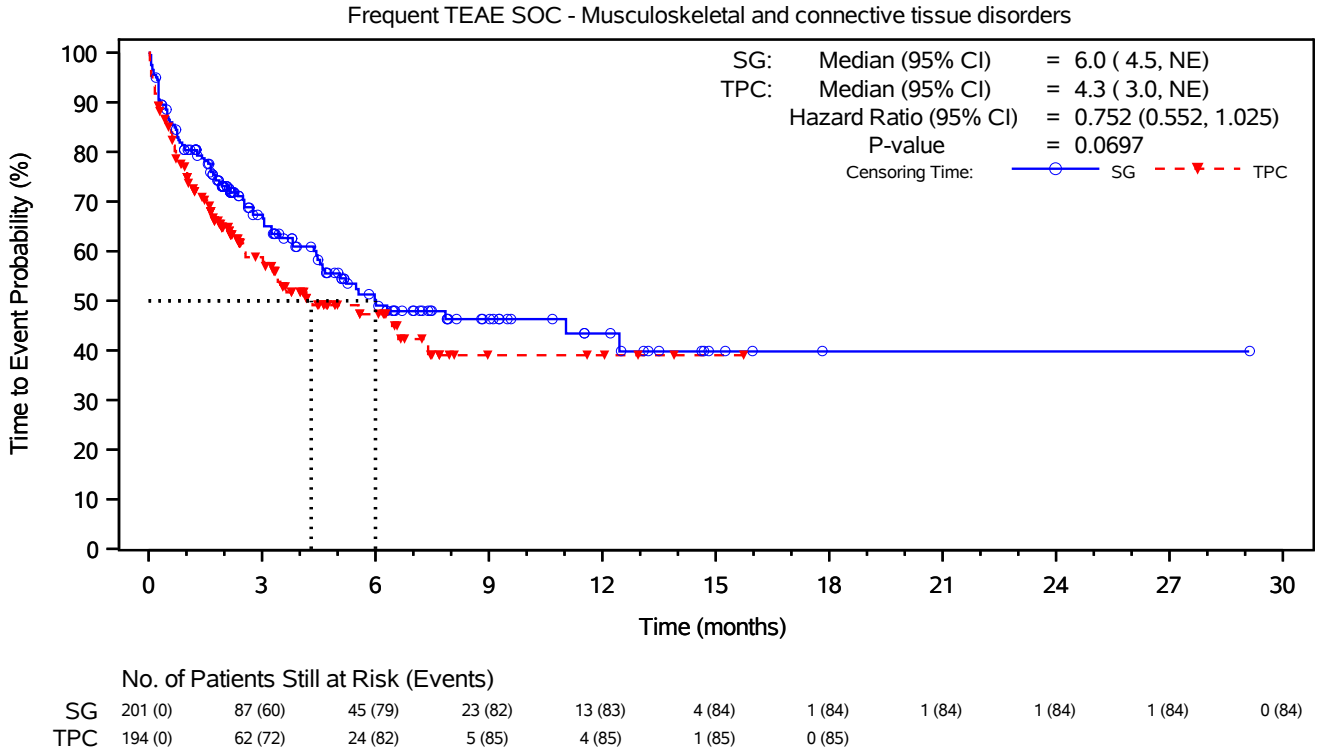

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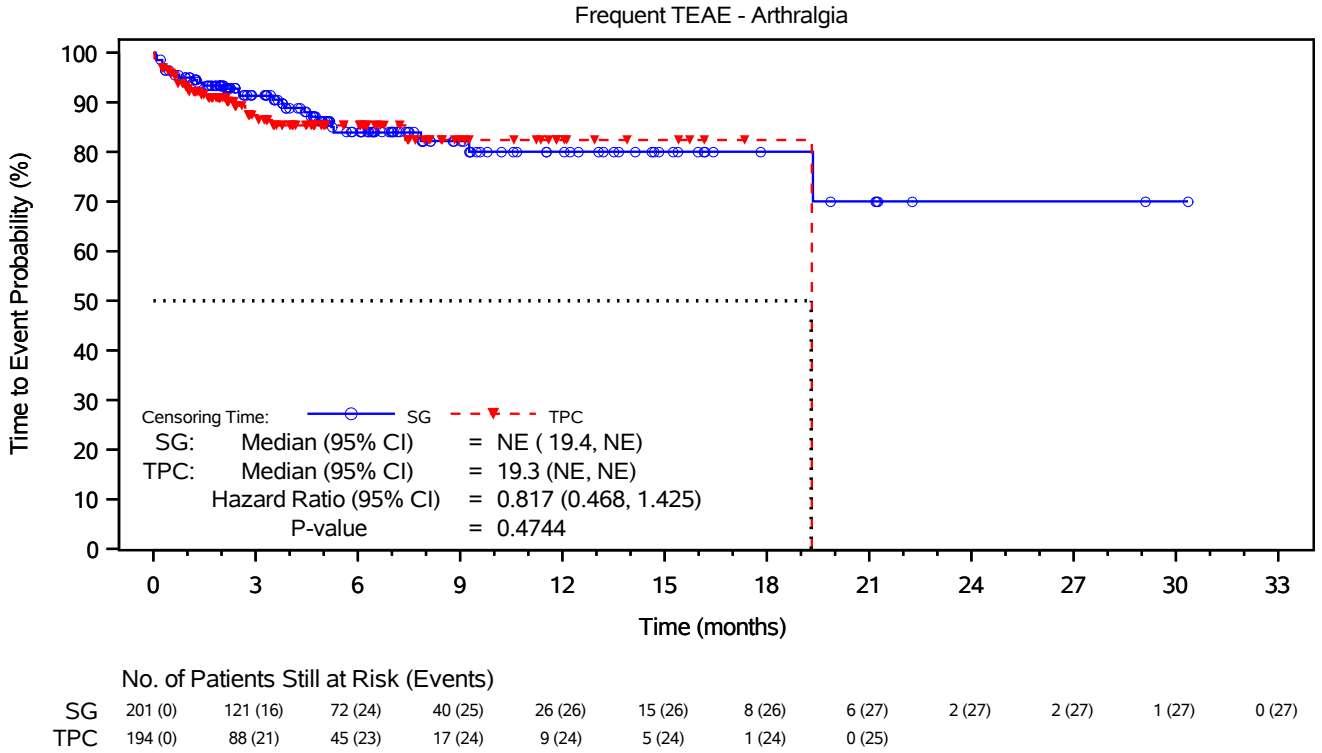

No. of Patients Still at Risk (Events)

SG	201 (0)	121 (16)	72 (24)	40 (25)	26 (26)	15 (26)	8 (26)	6 (27)	2 (27)	2 (27)	1 (27)	0 (27)
TPC	194 (0)	88 (21)	45 (23)	17 (24)	9 (24)	5 (24)	1 (24)	0 (25)				

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Safety Population
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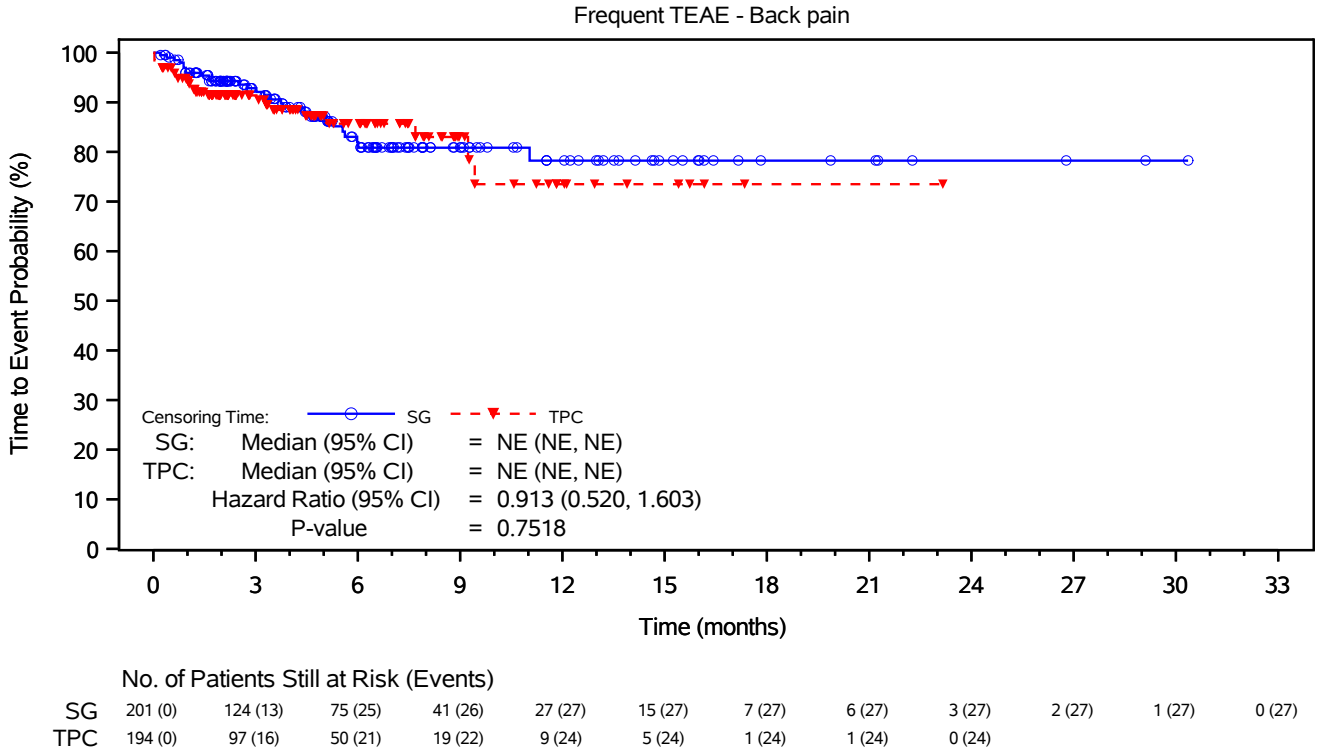

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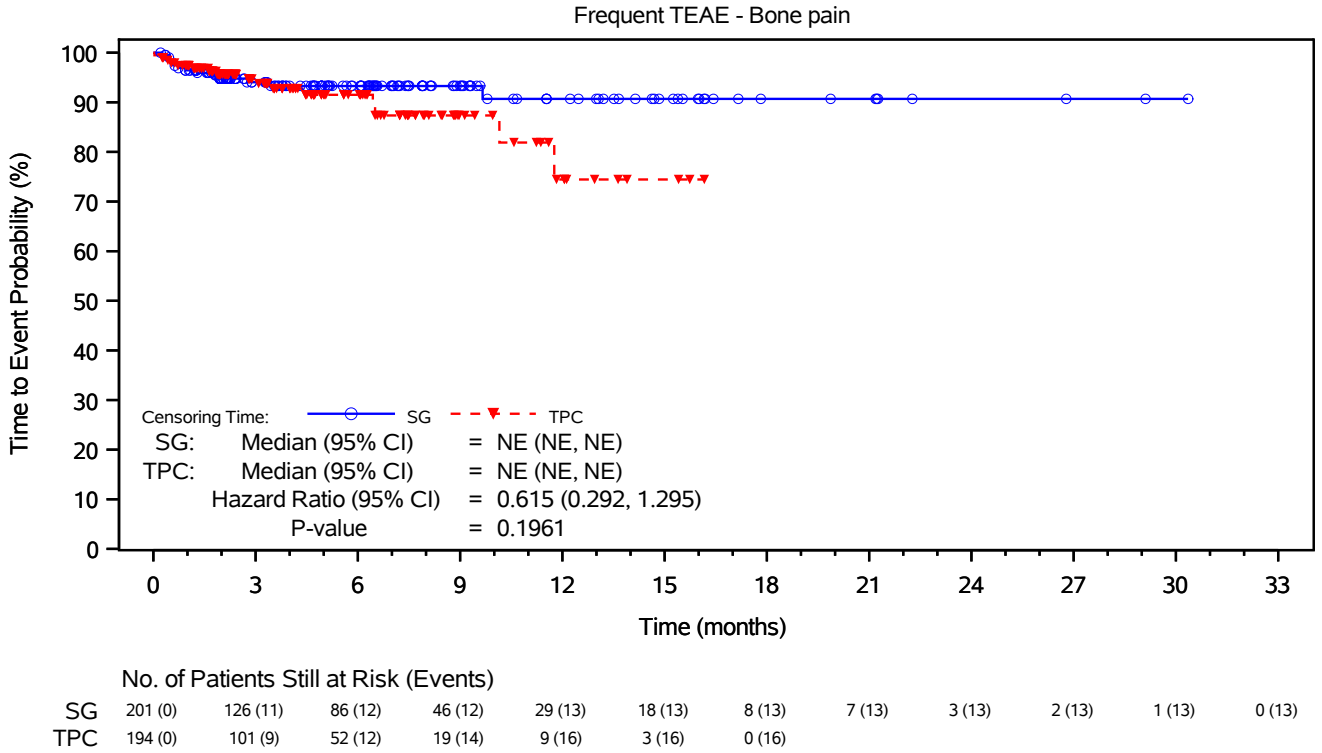

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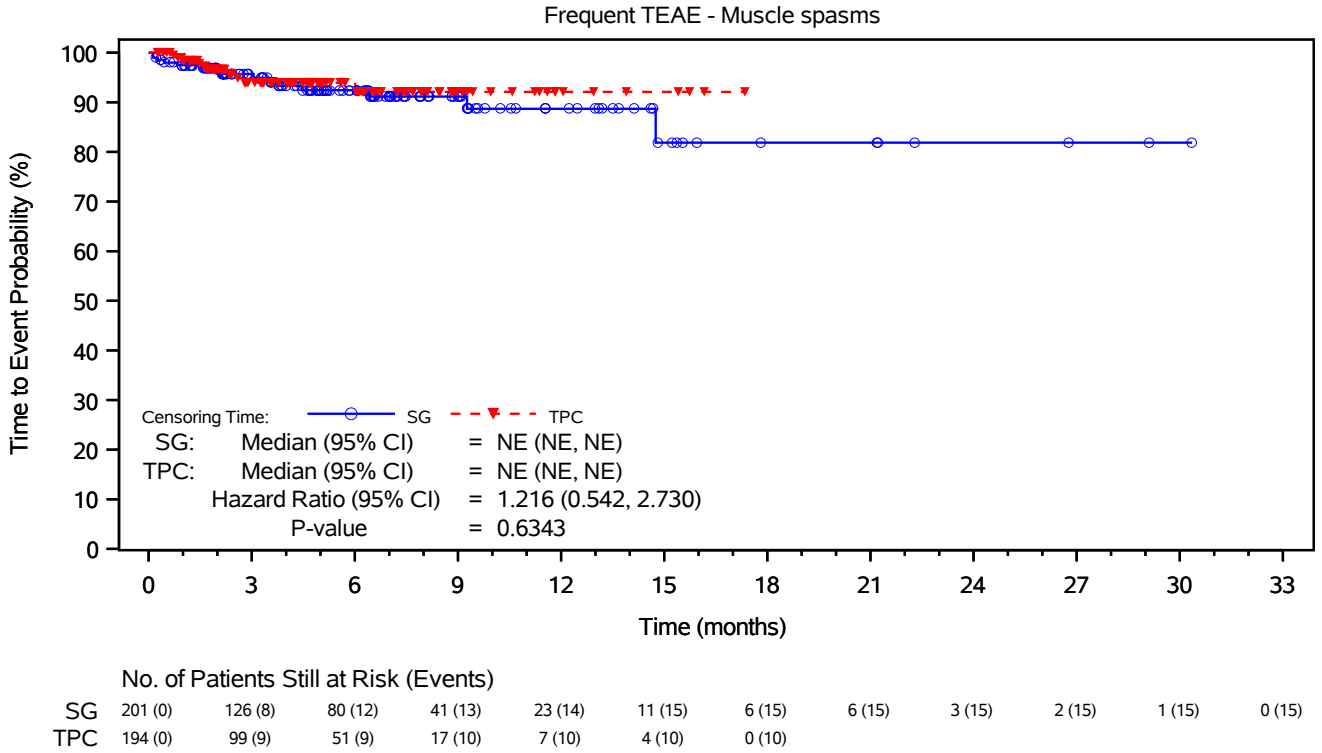

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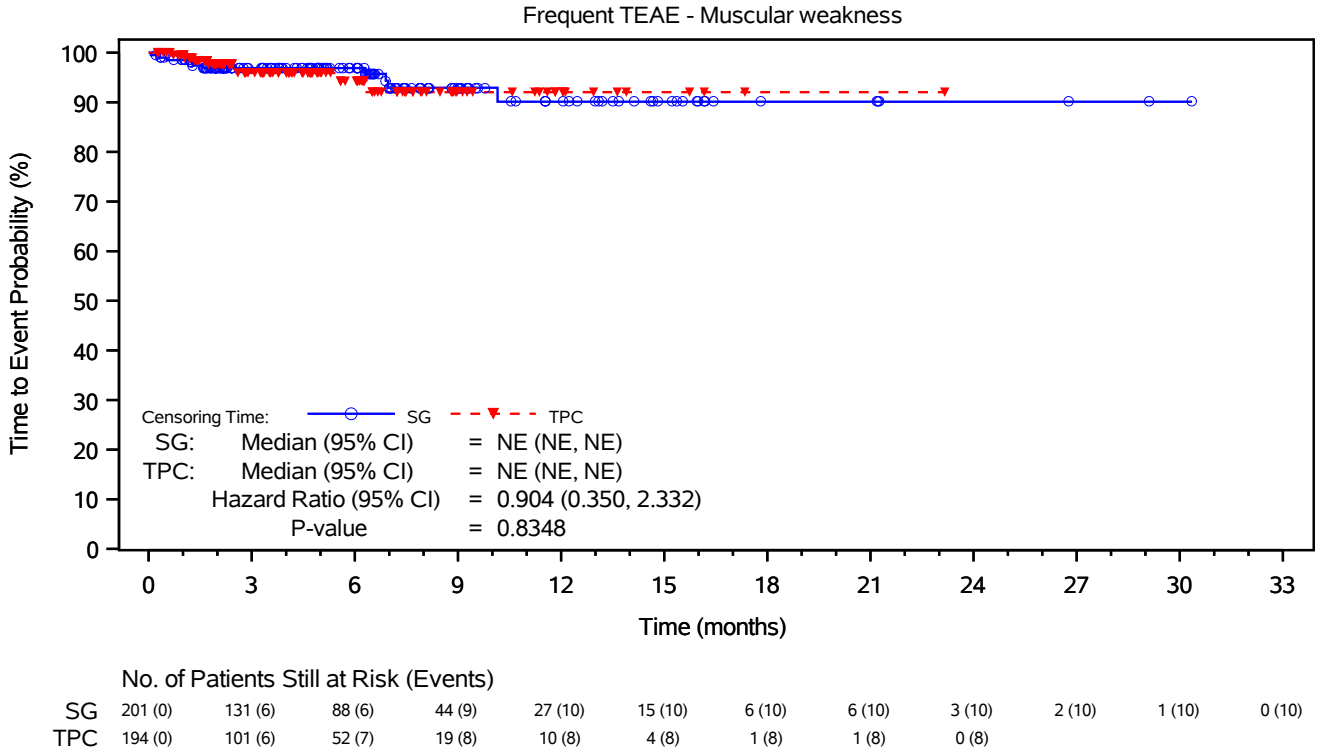

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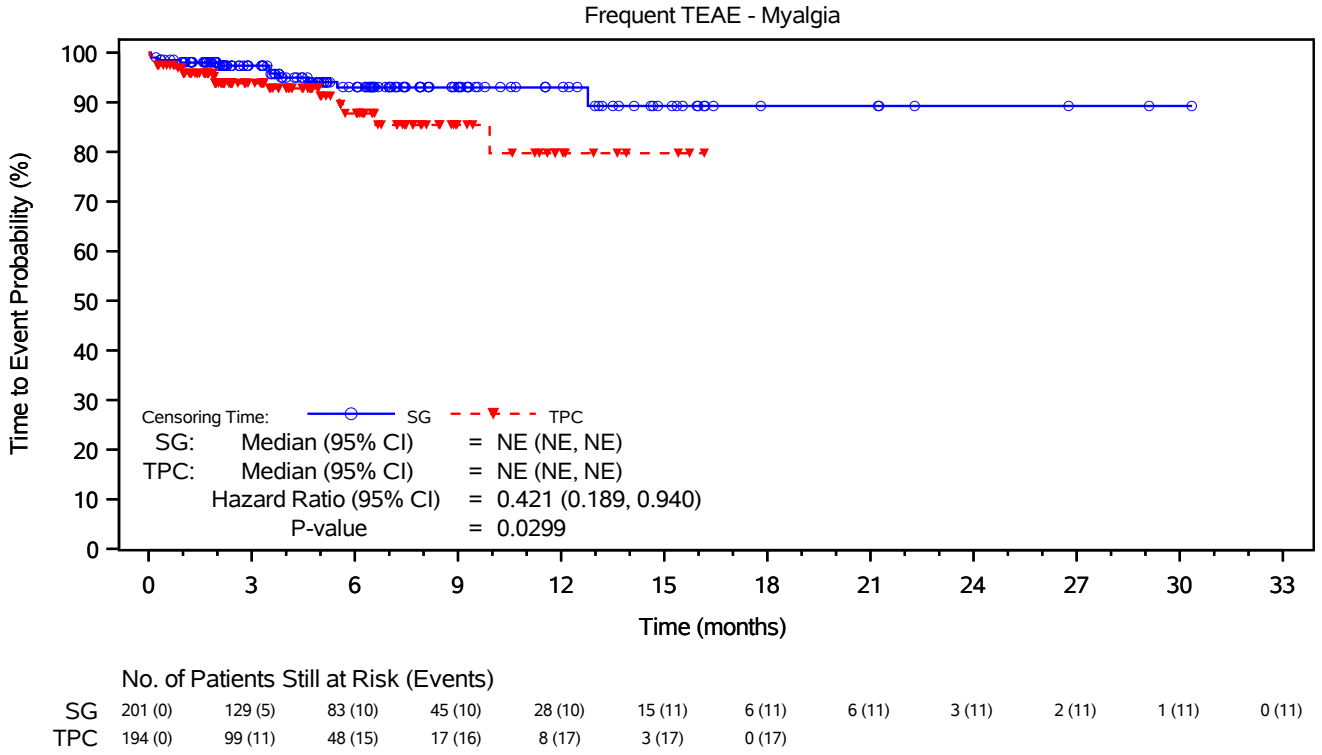

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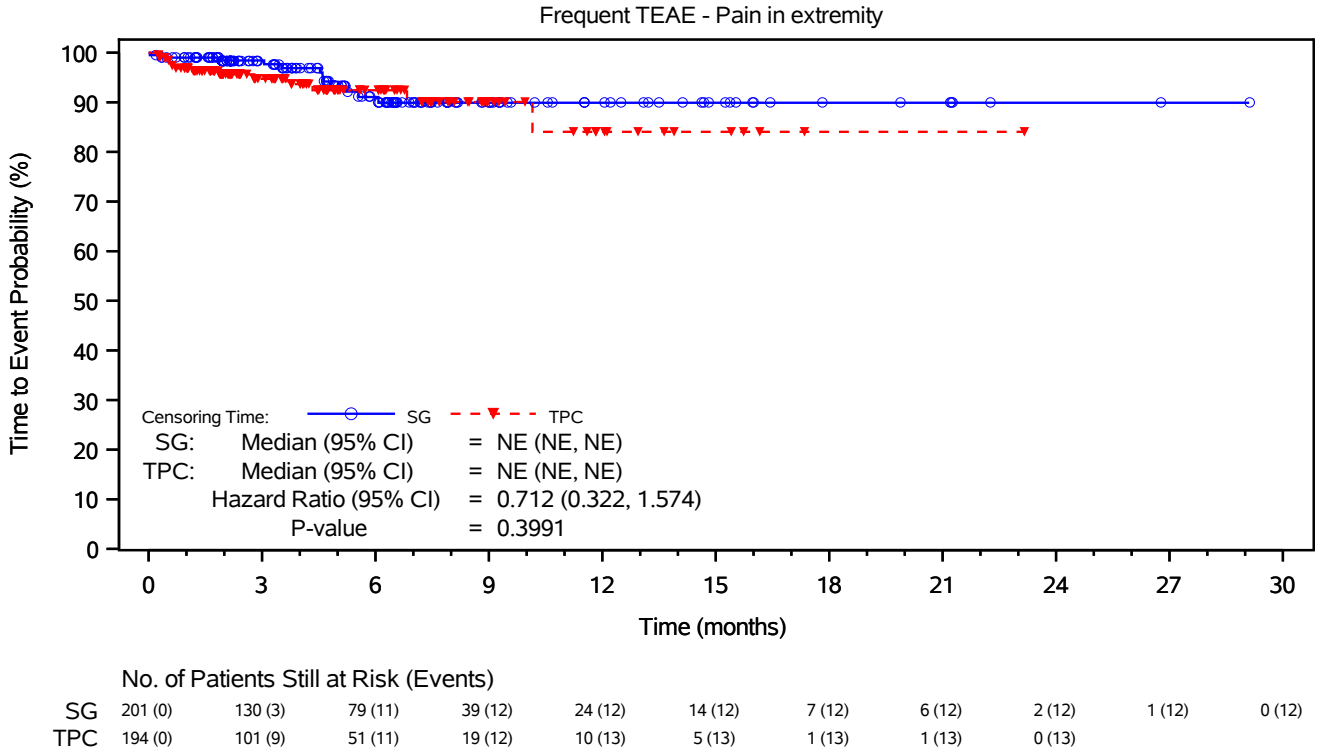

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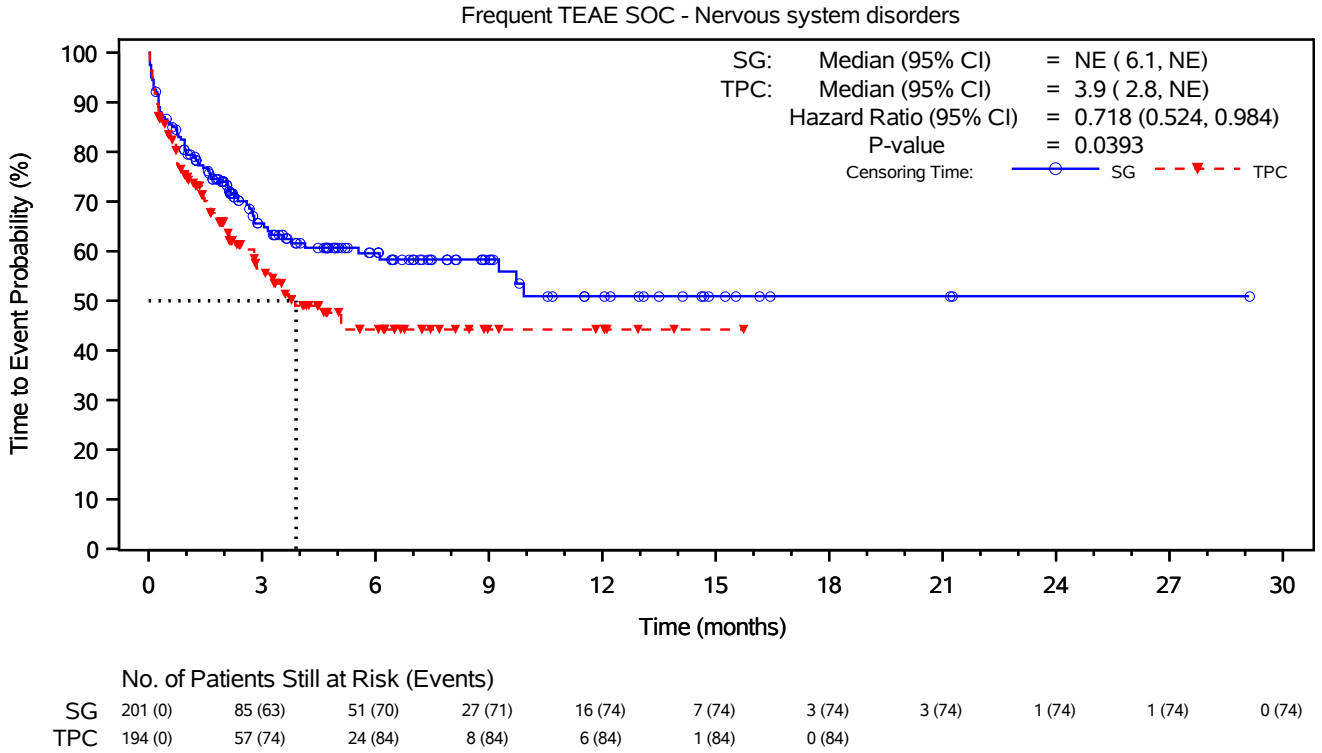

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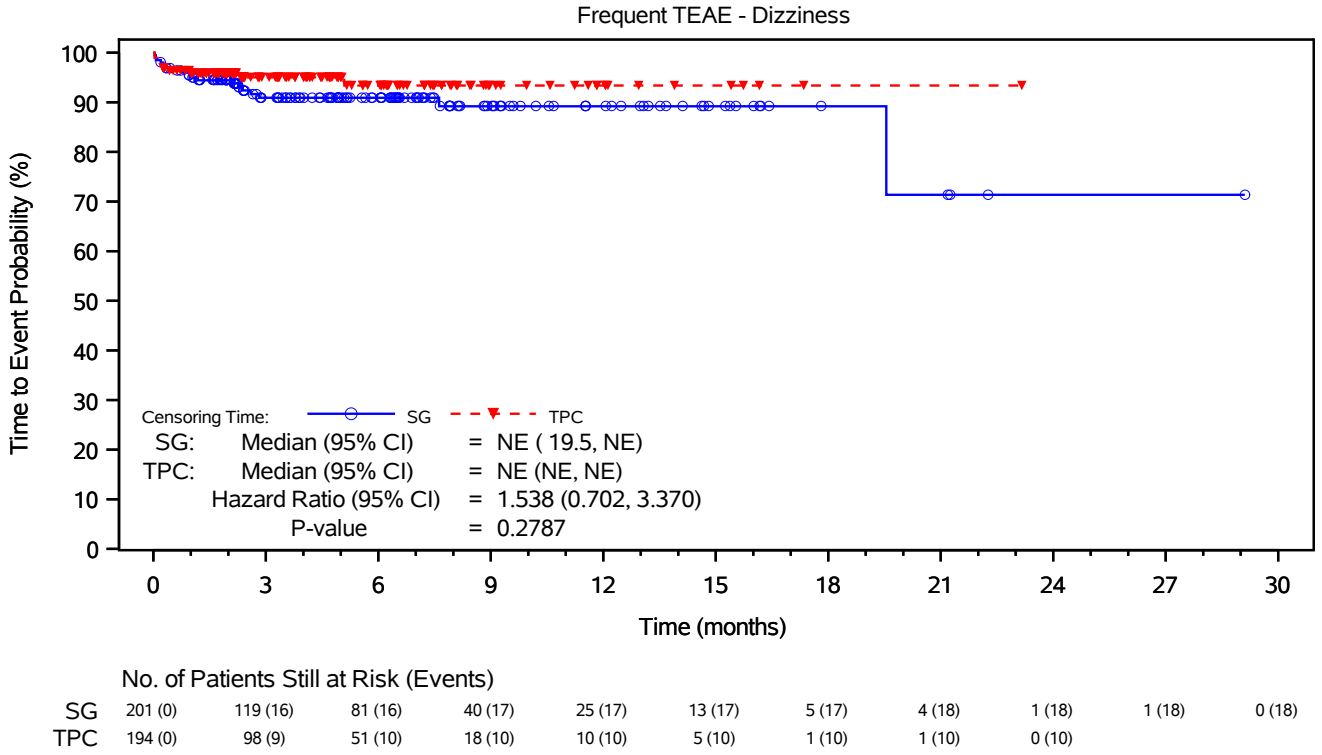

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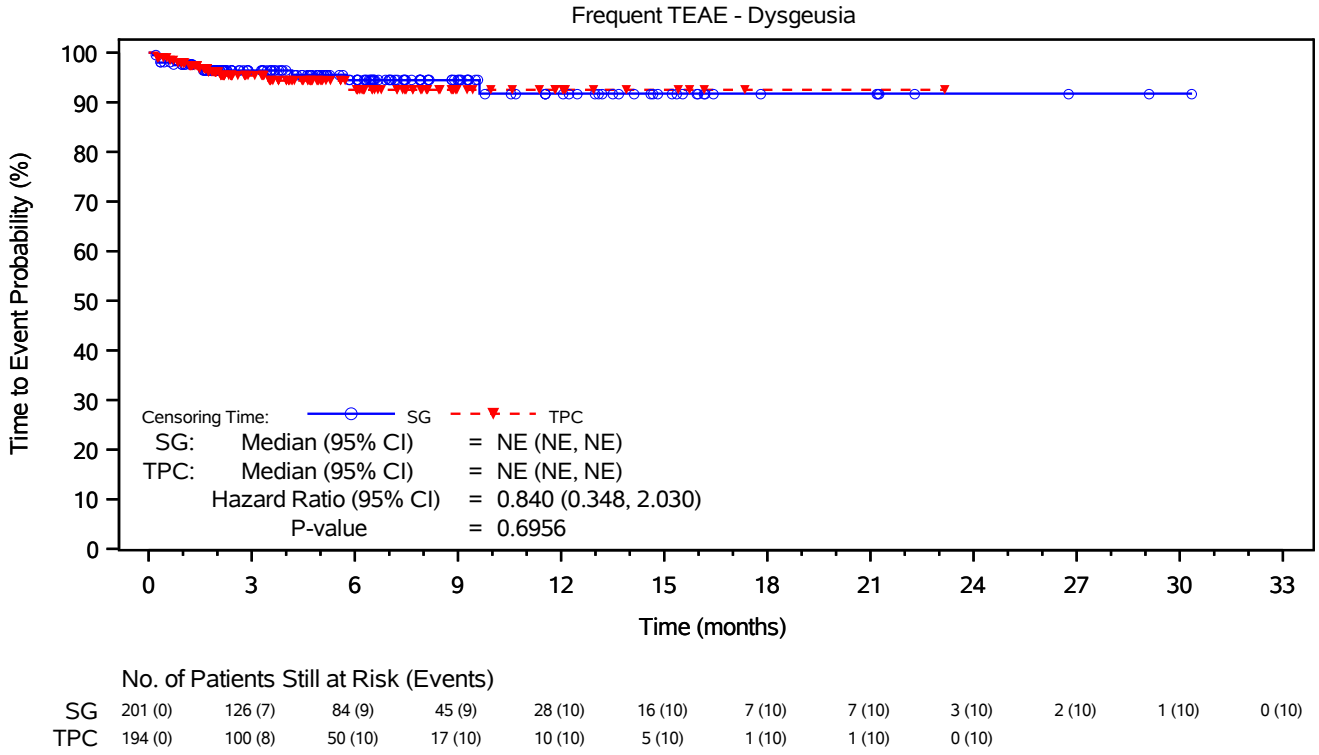

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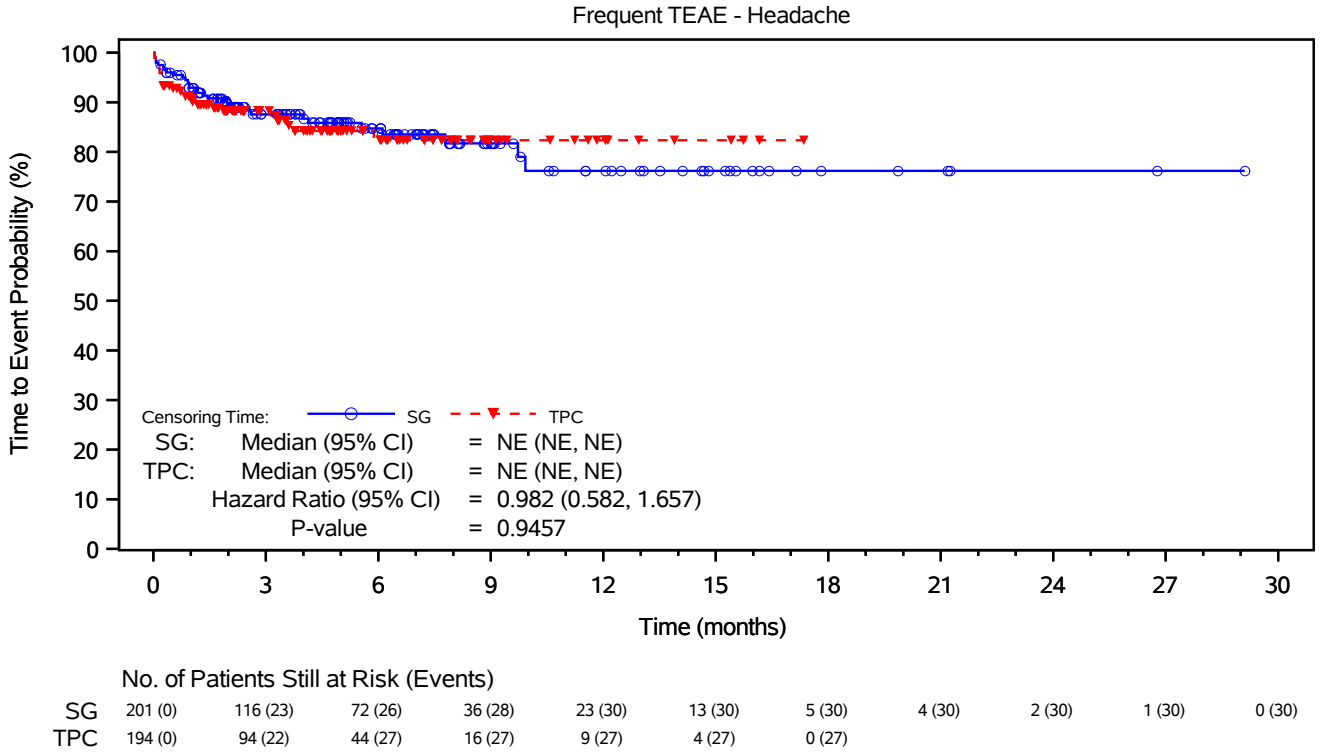

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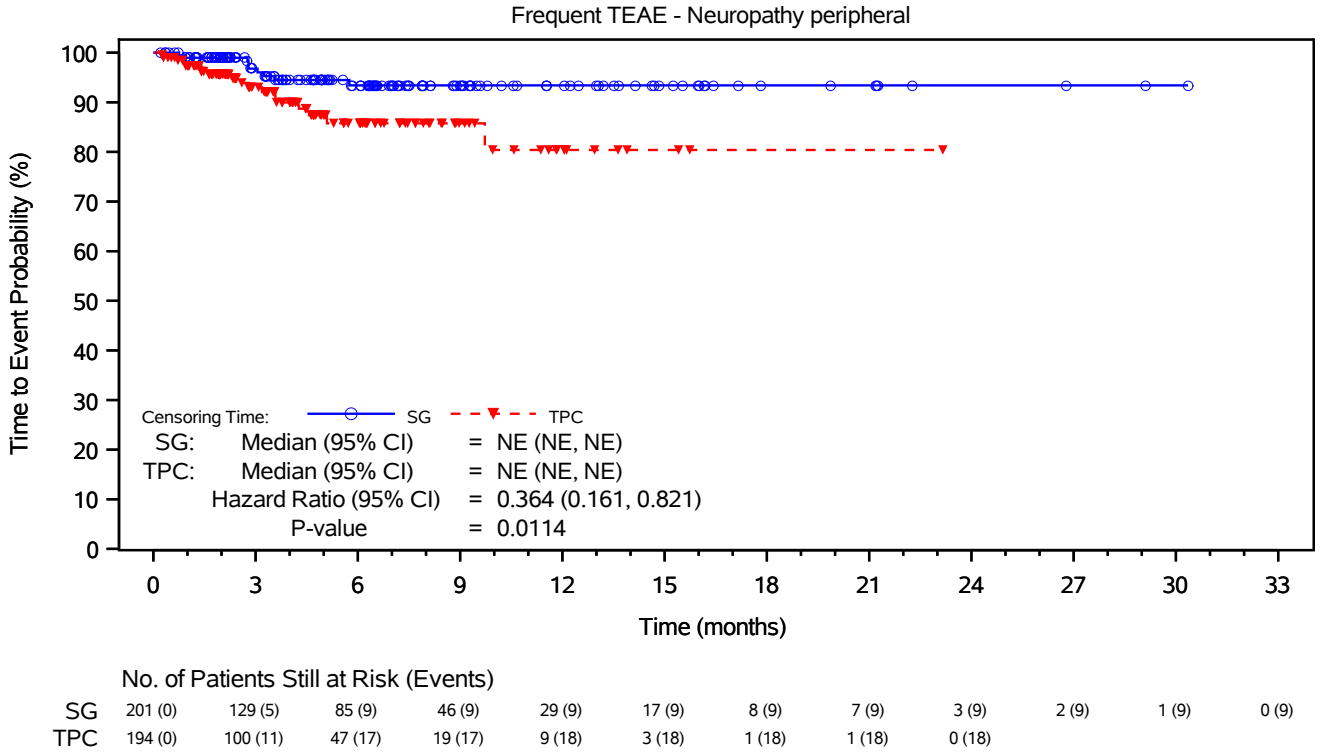

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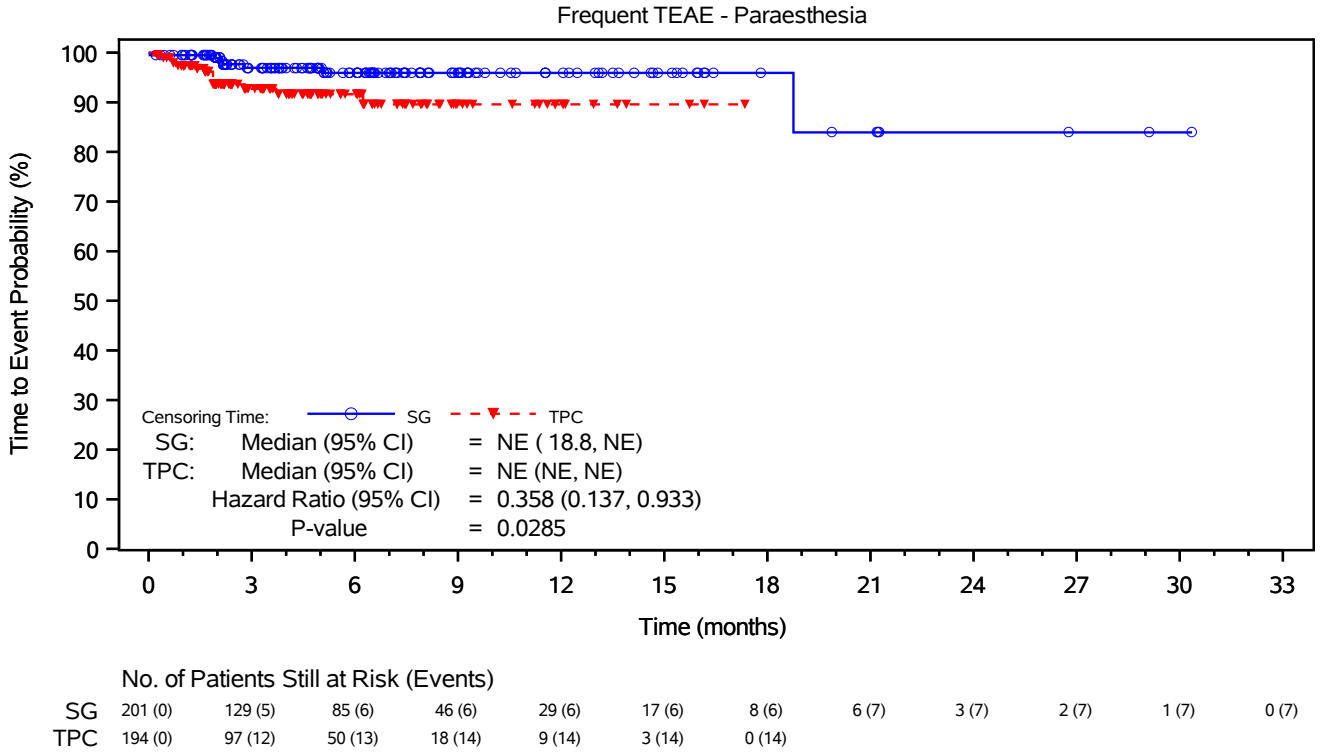

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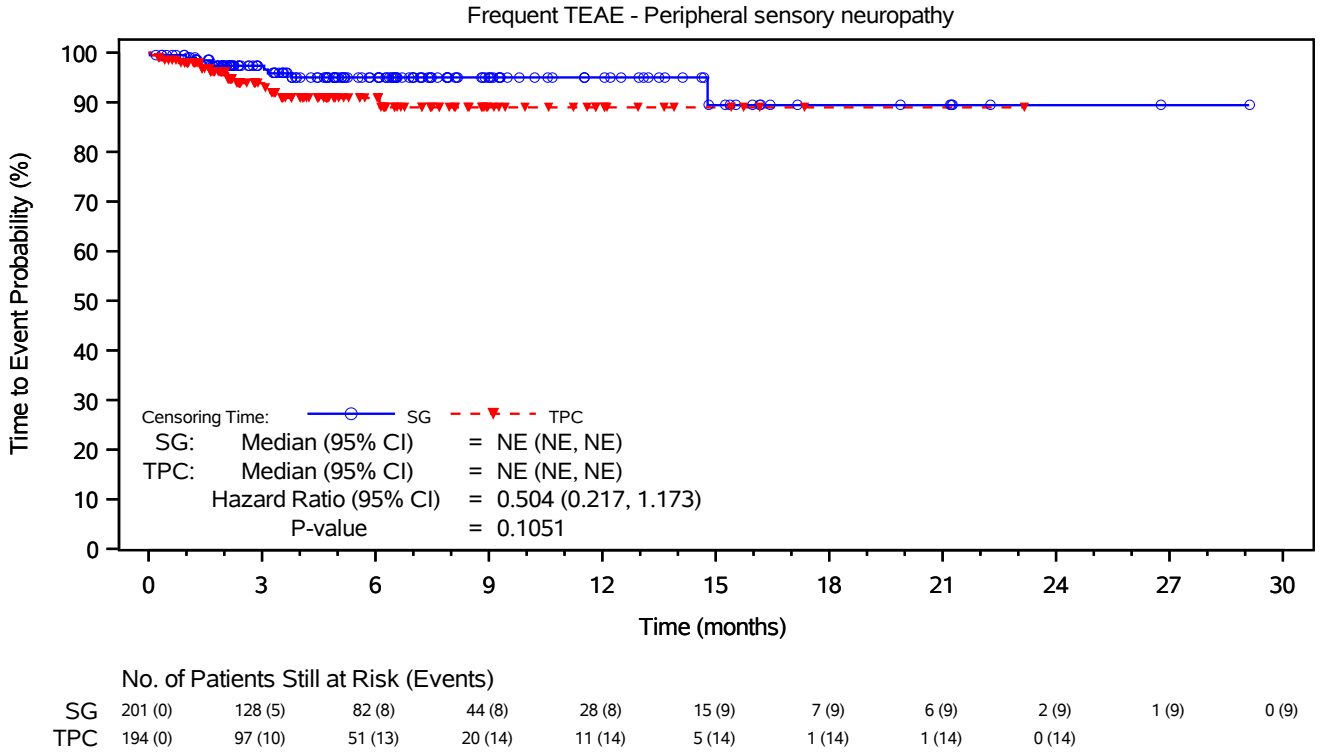

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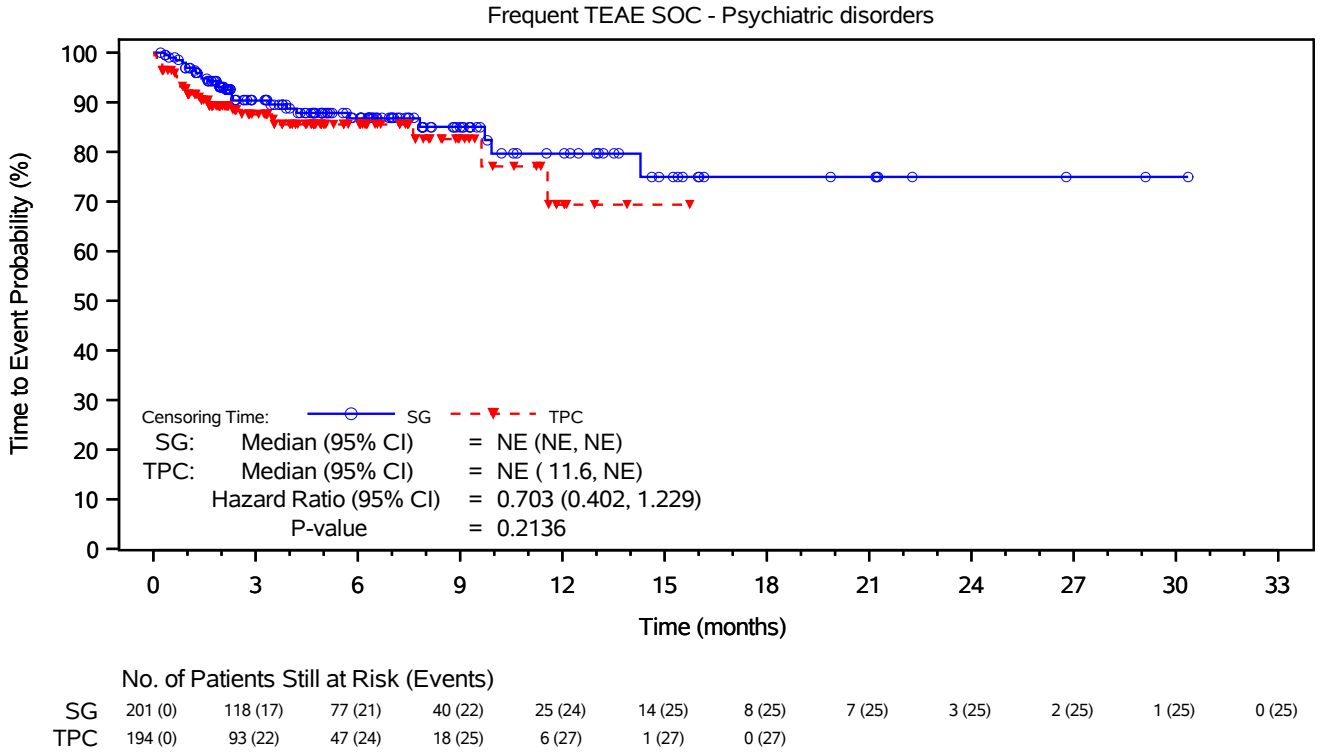
Figure 15.11.7.1: KM Plot for Time to the First Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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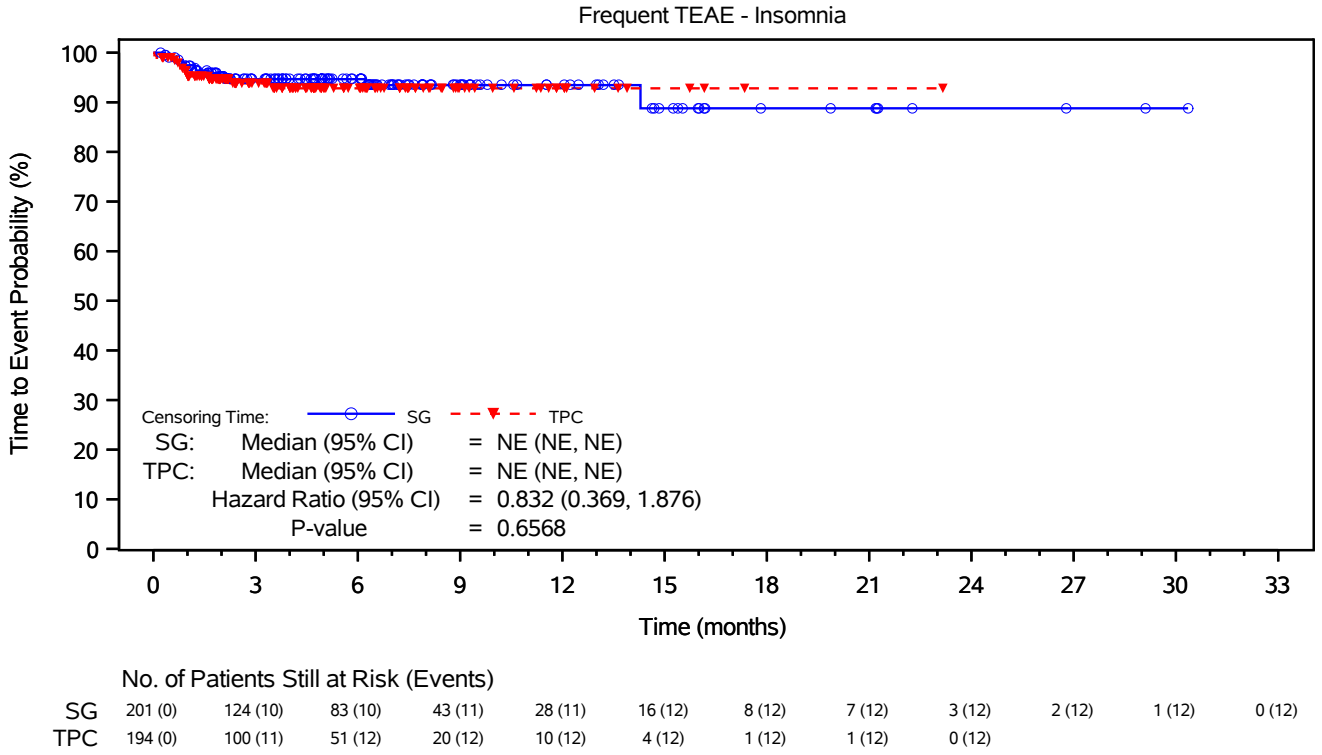

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NE = not estimable.
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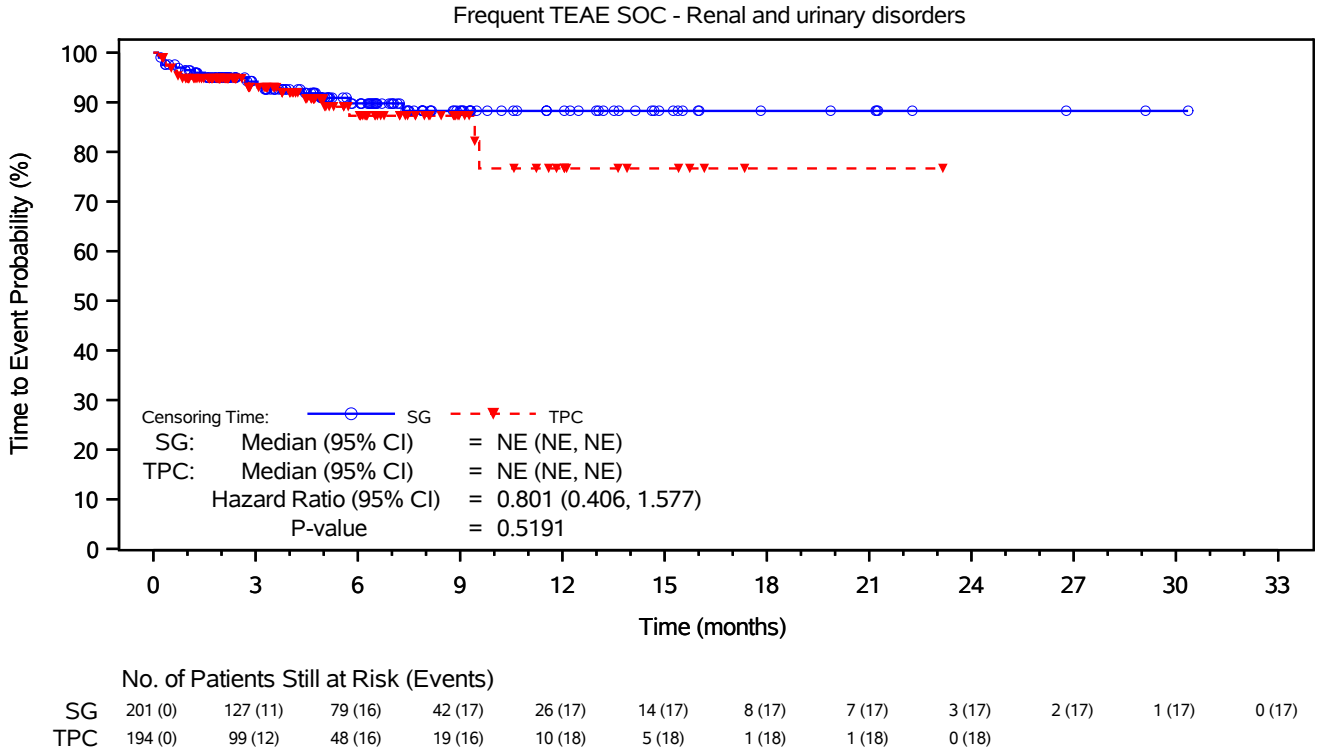

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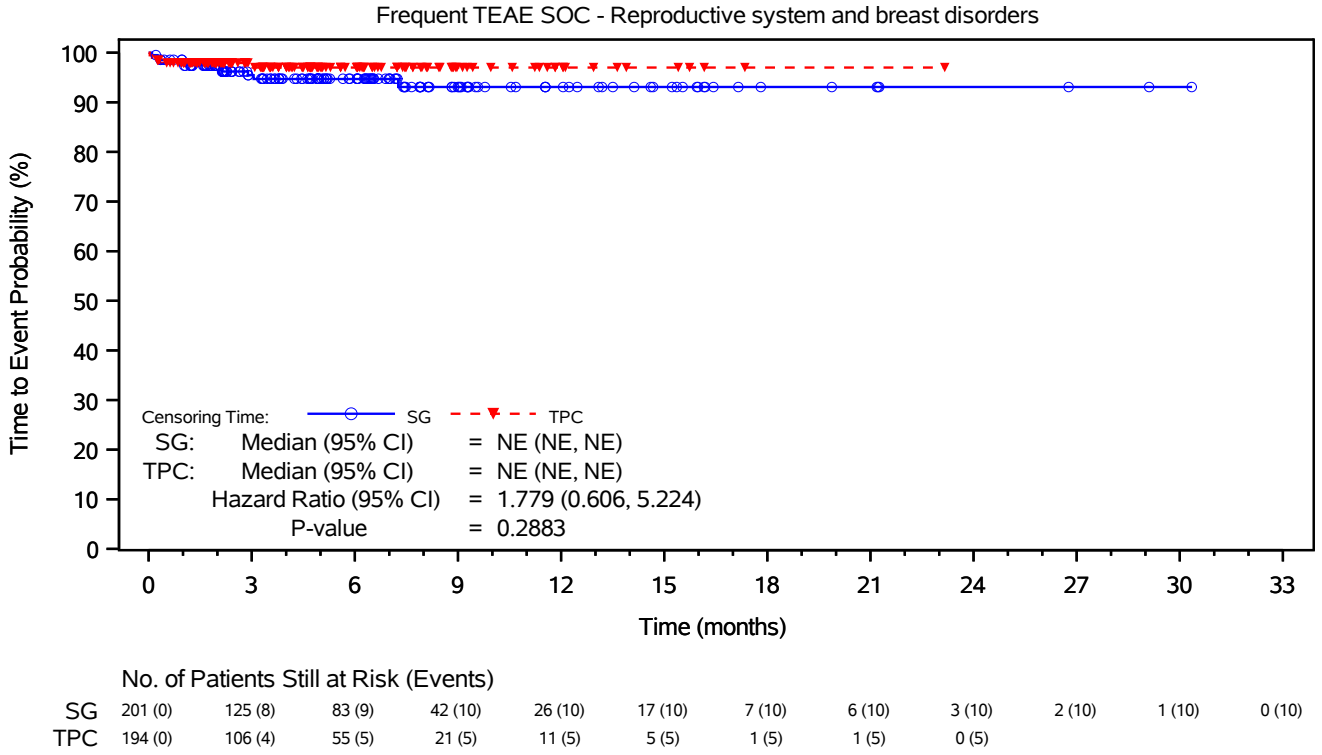

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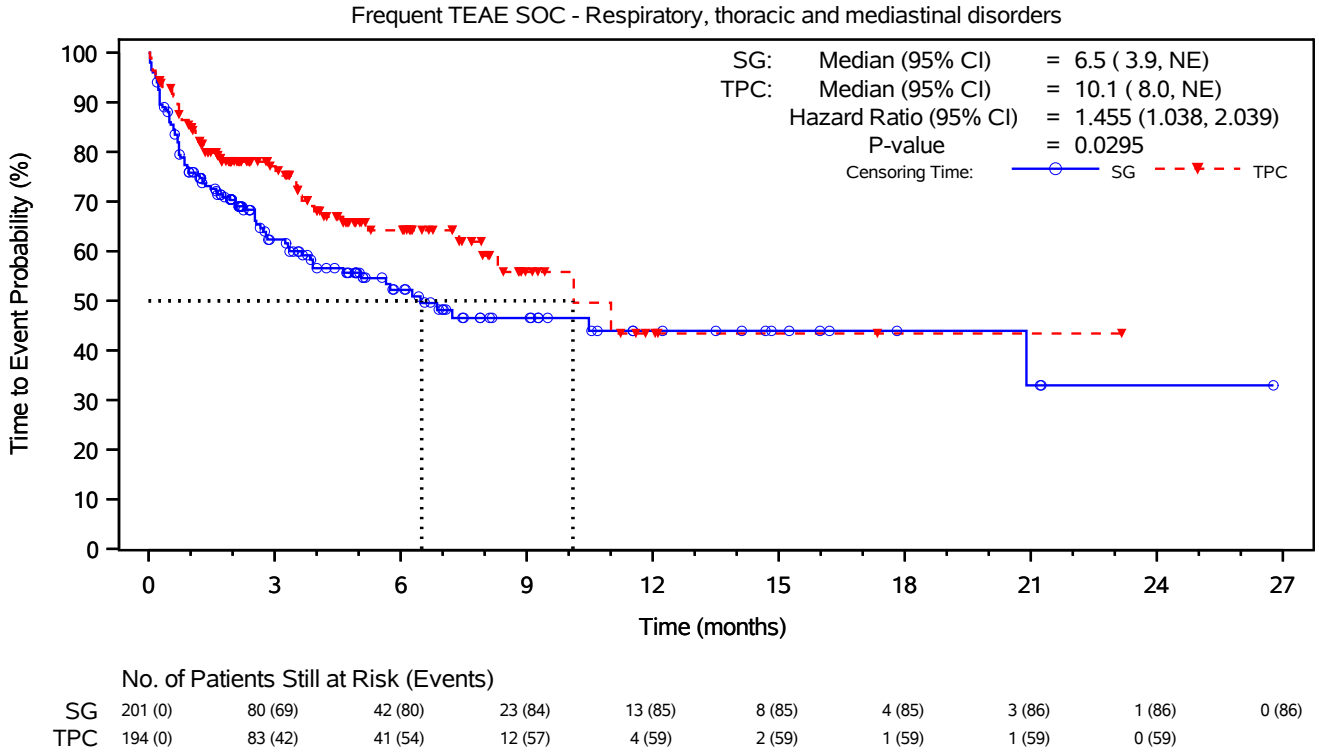

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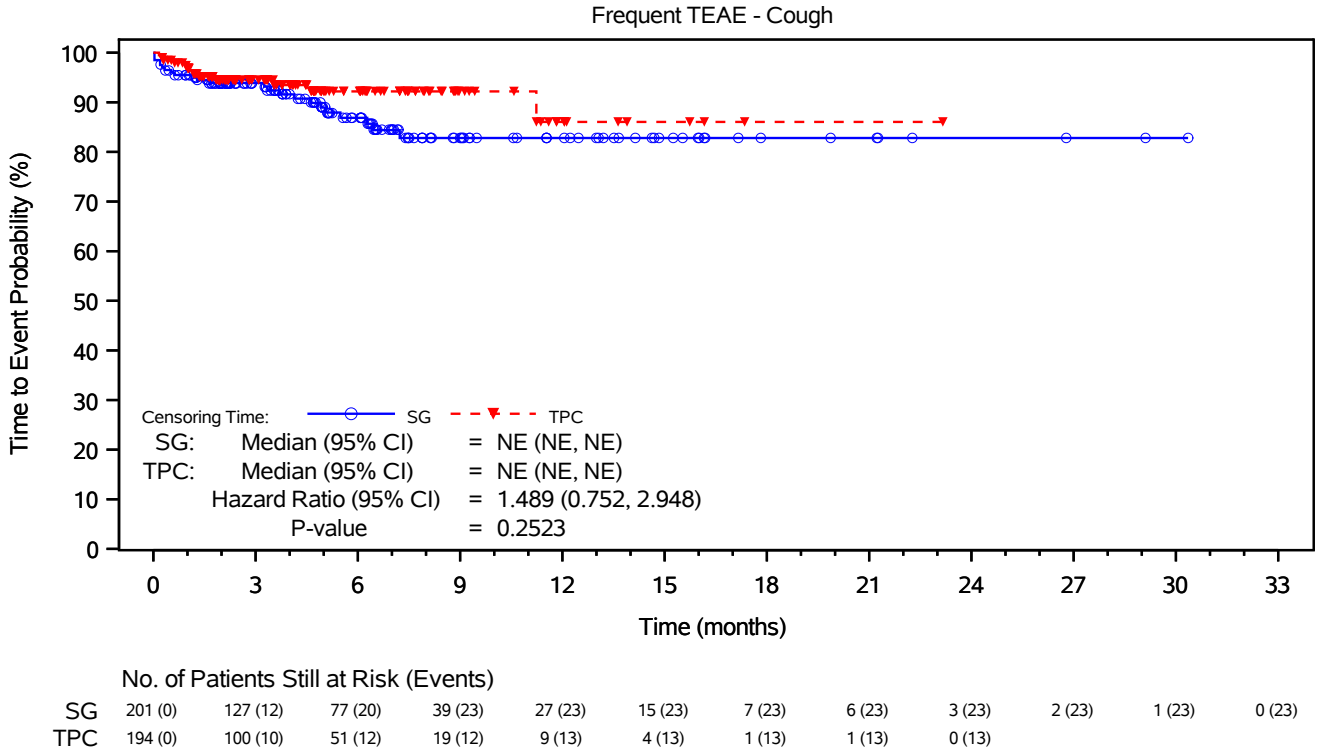

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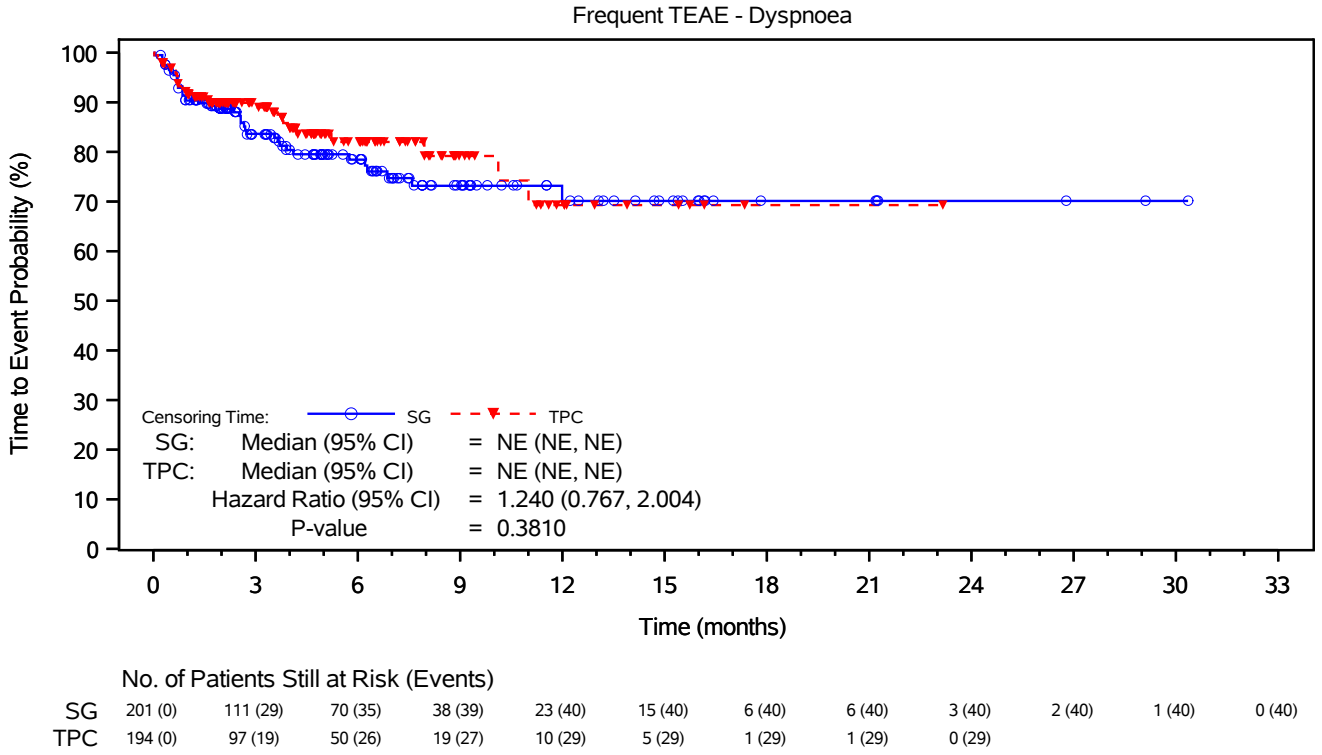

No. of Patients Still at Risk (Events)

SG	201 (0)	111 (29)	70 (35)	38 (39)	23 (40)	15 (40)	6 (40)	6 (40)	3 (40)	2 (40)	1 (40)	0 (40)
TPC	194 (0)	97 (19)	50 (26)	19 (27)	10 (29)	5 (29)	1 (29)	1 (29)	0 (29)			

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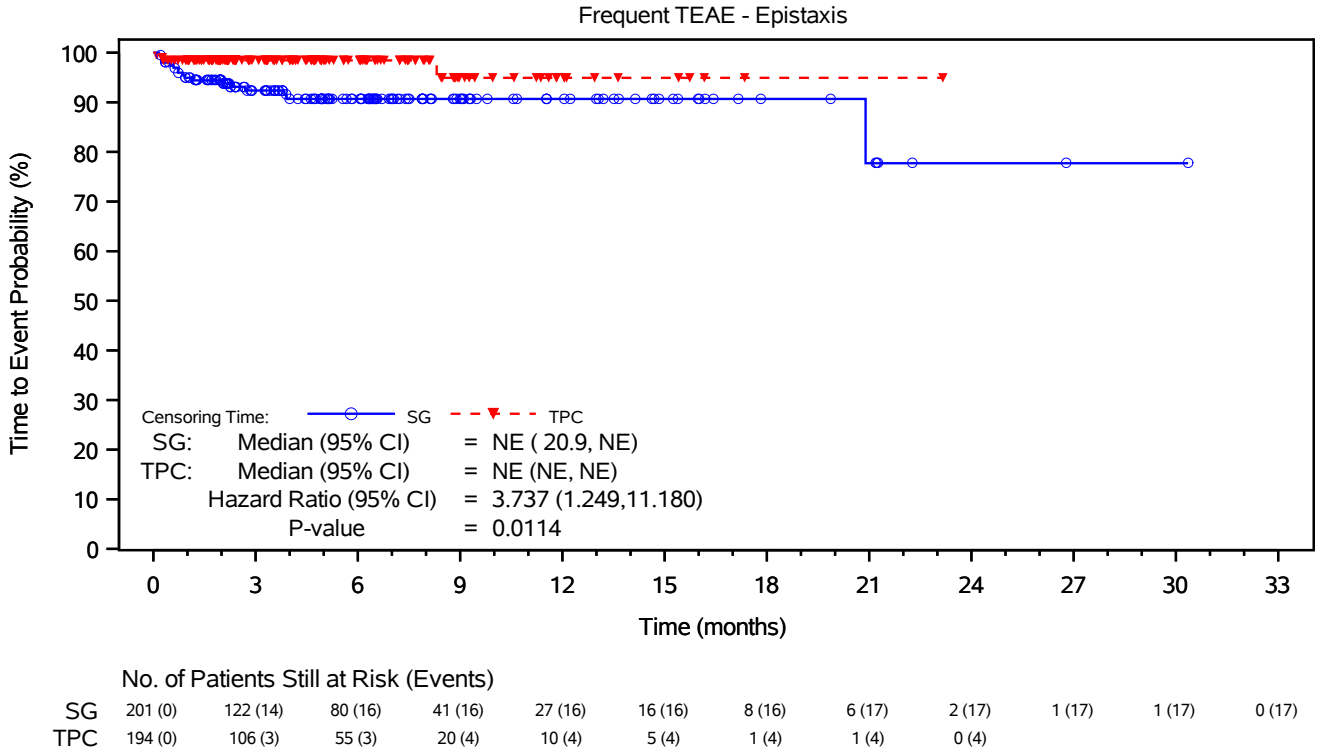

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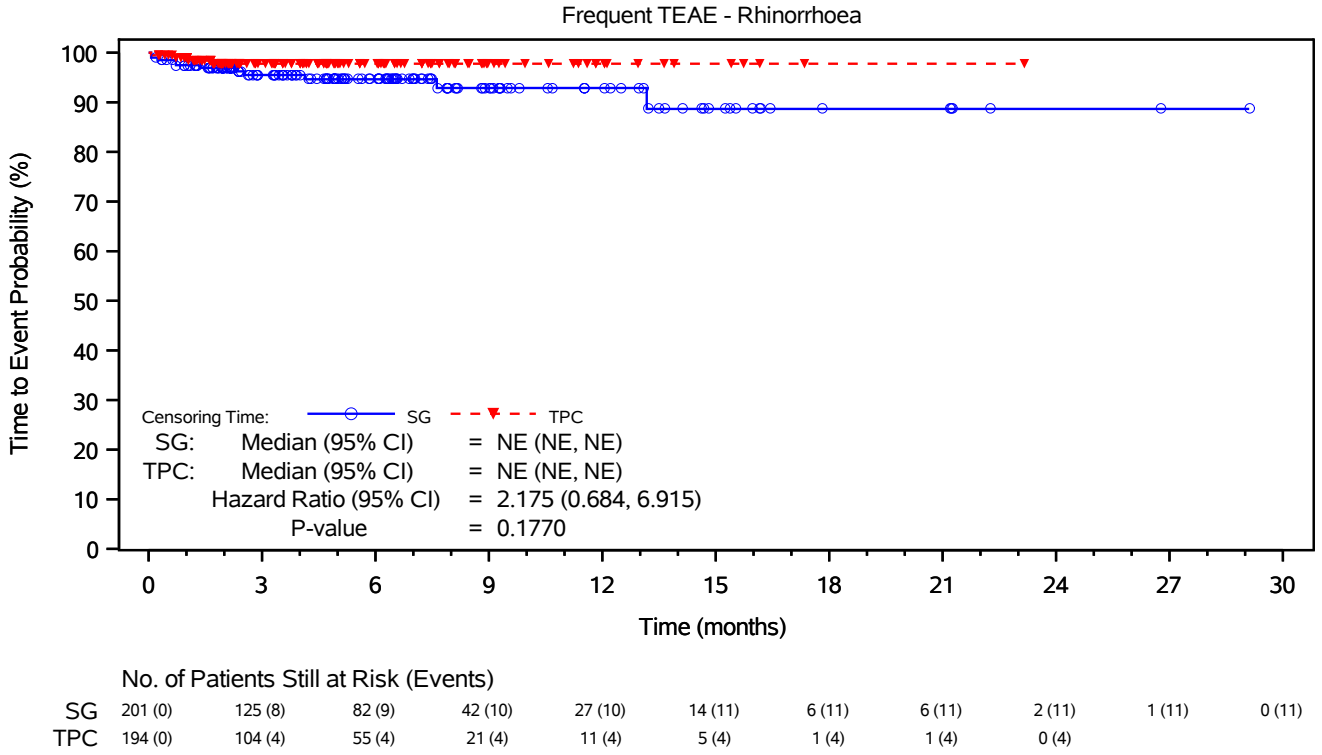

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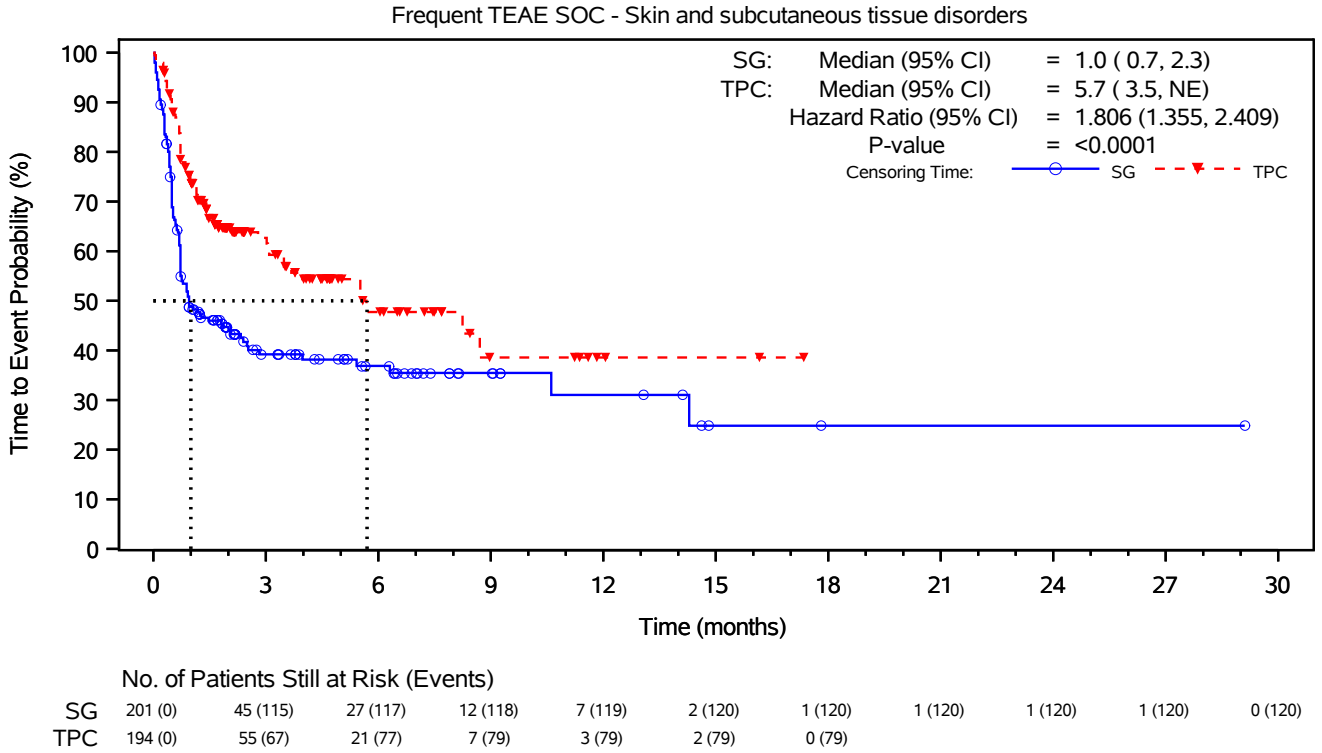

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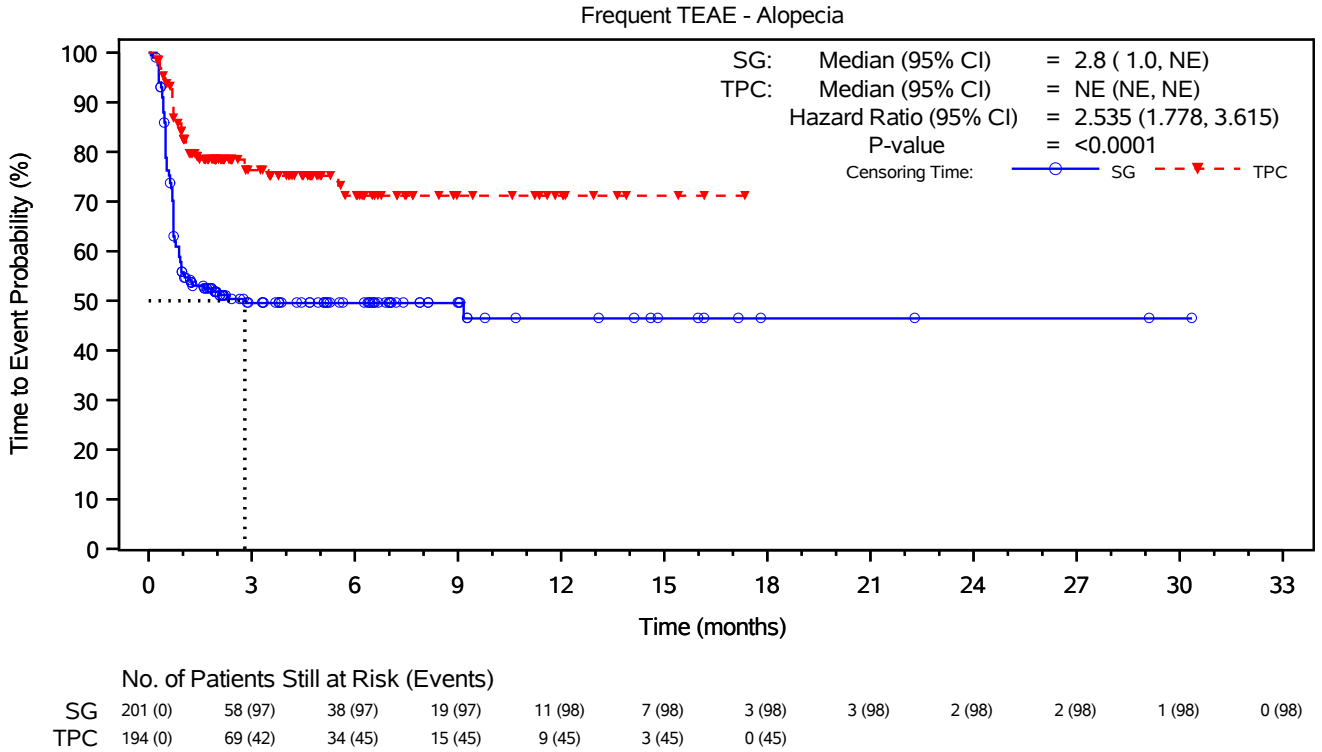

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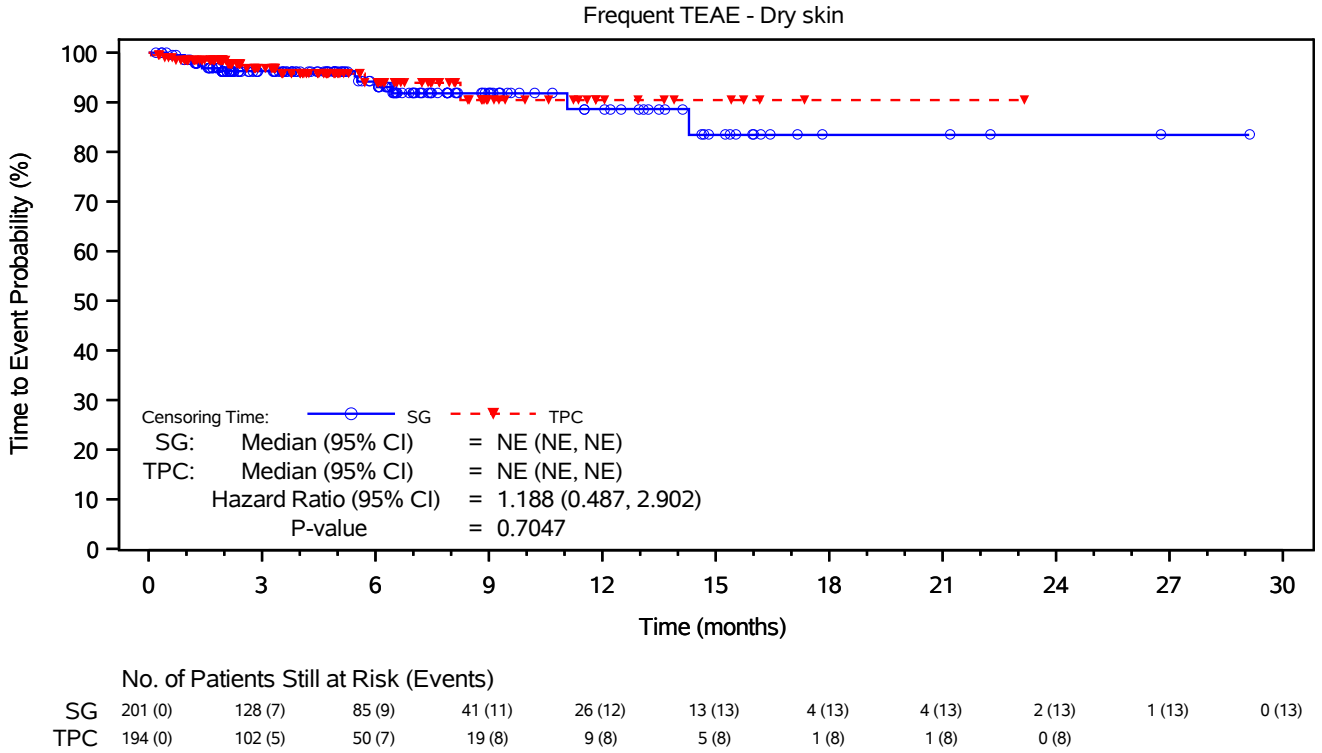

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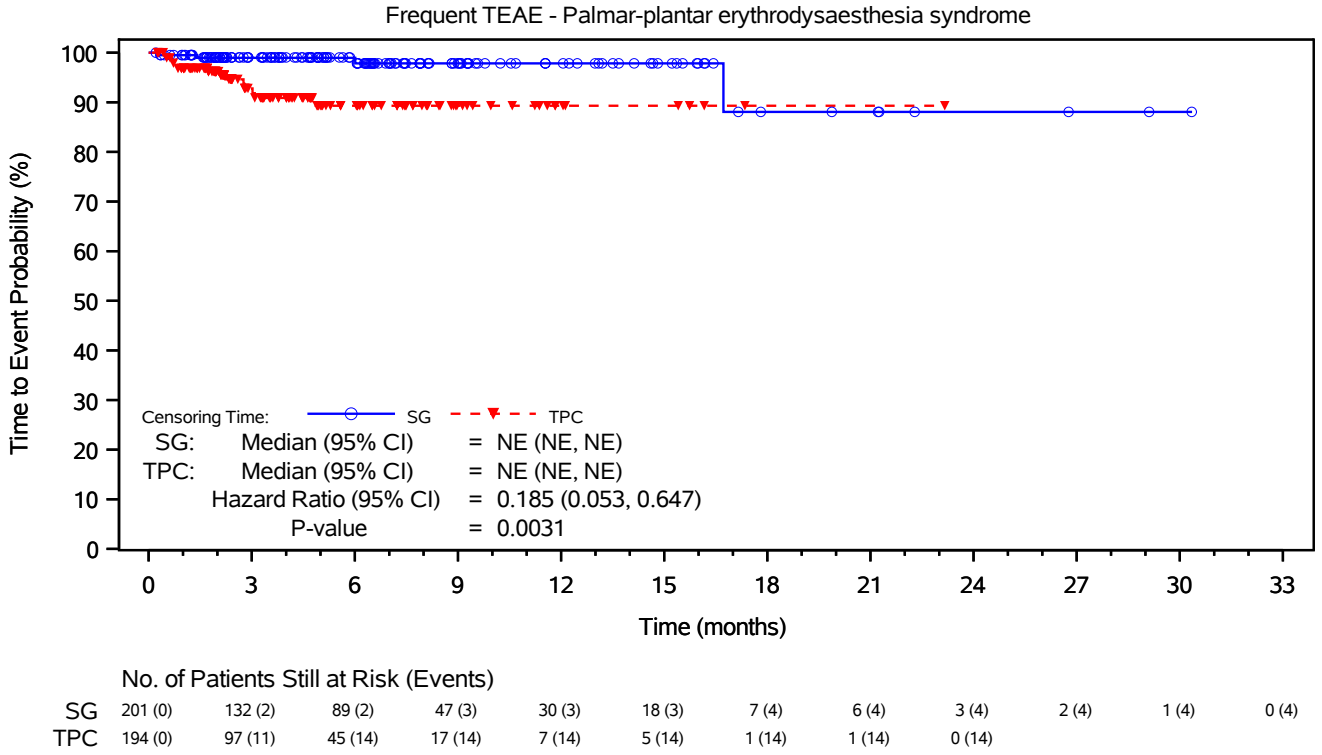

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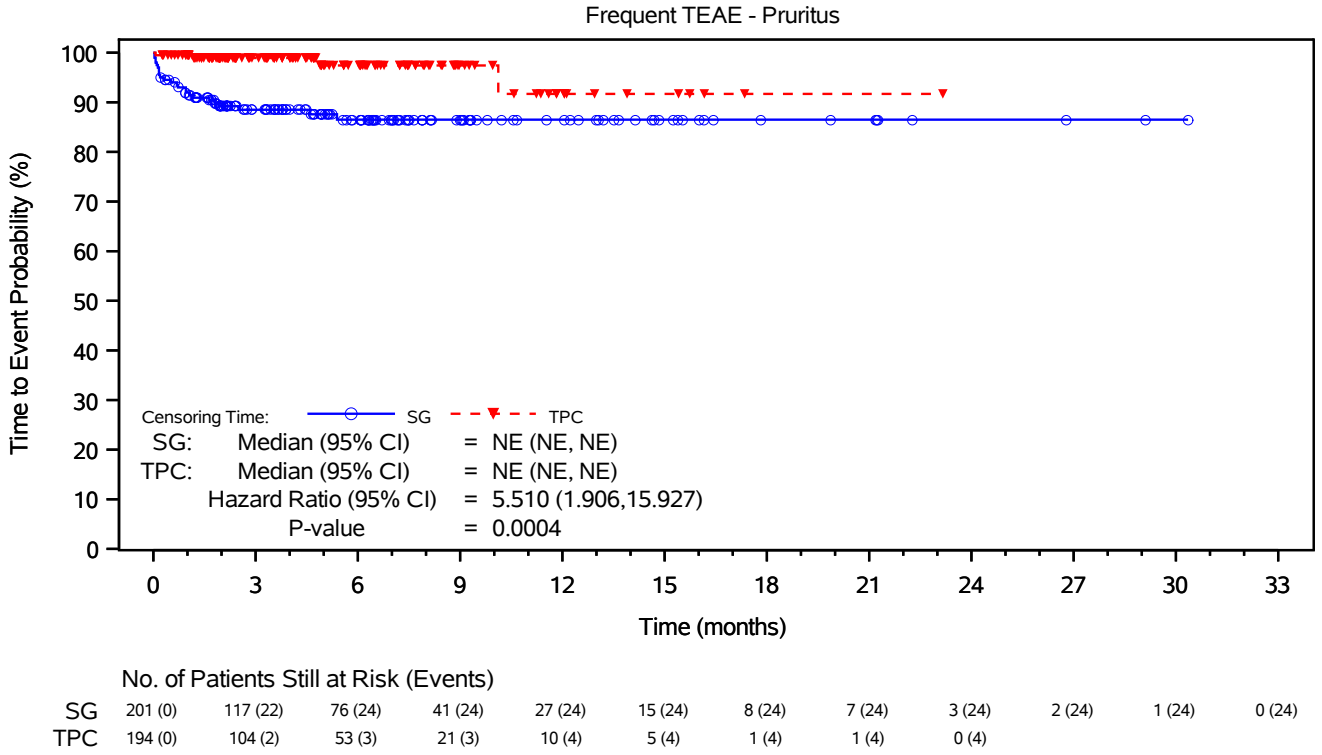

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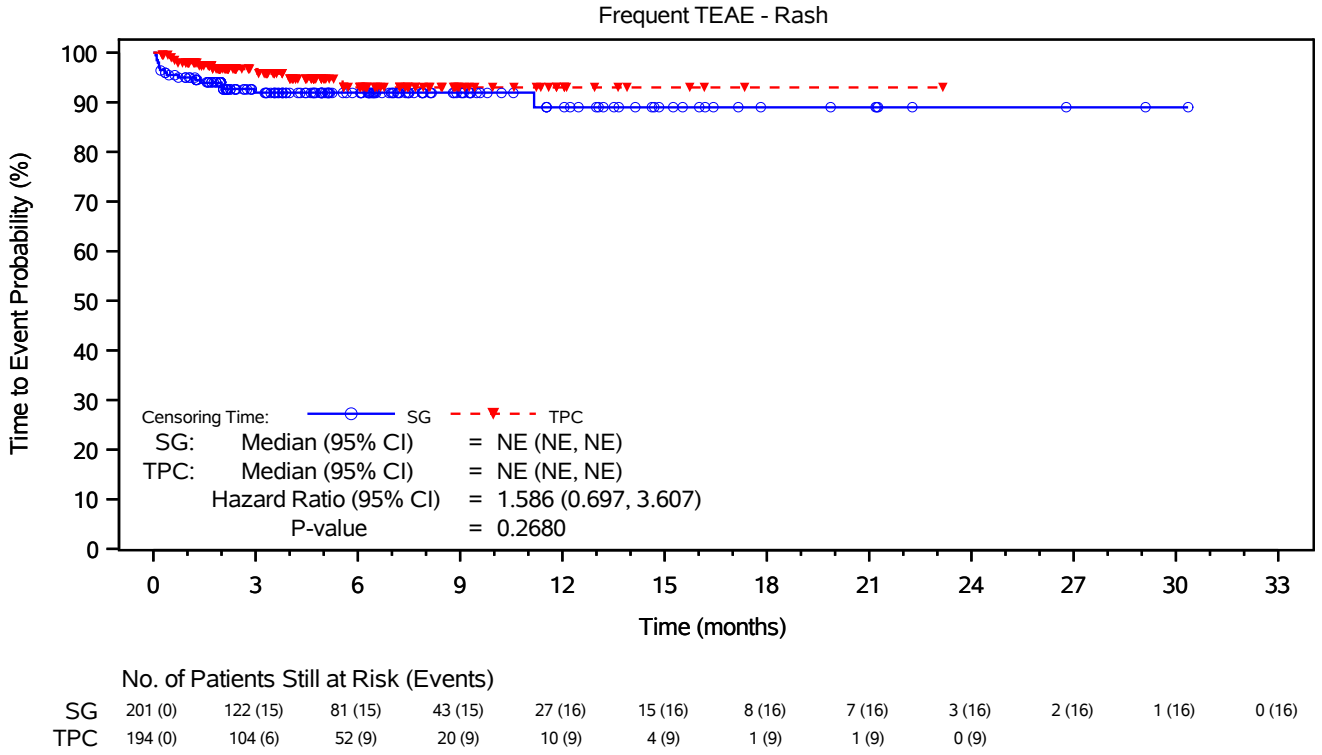

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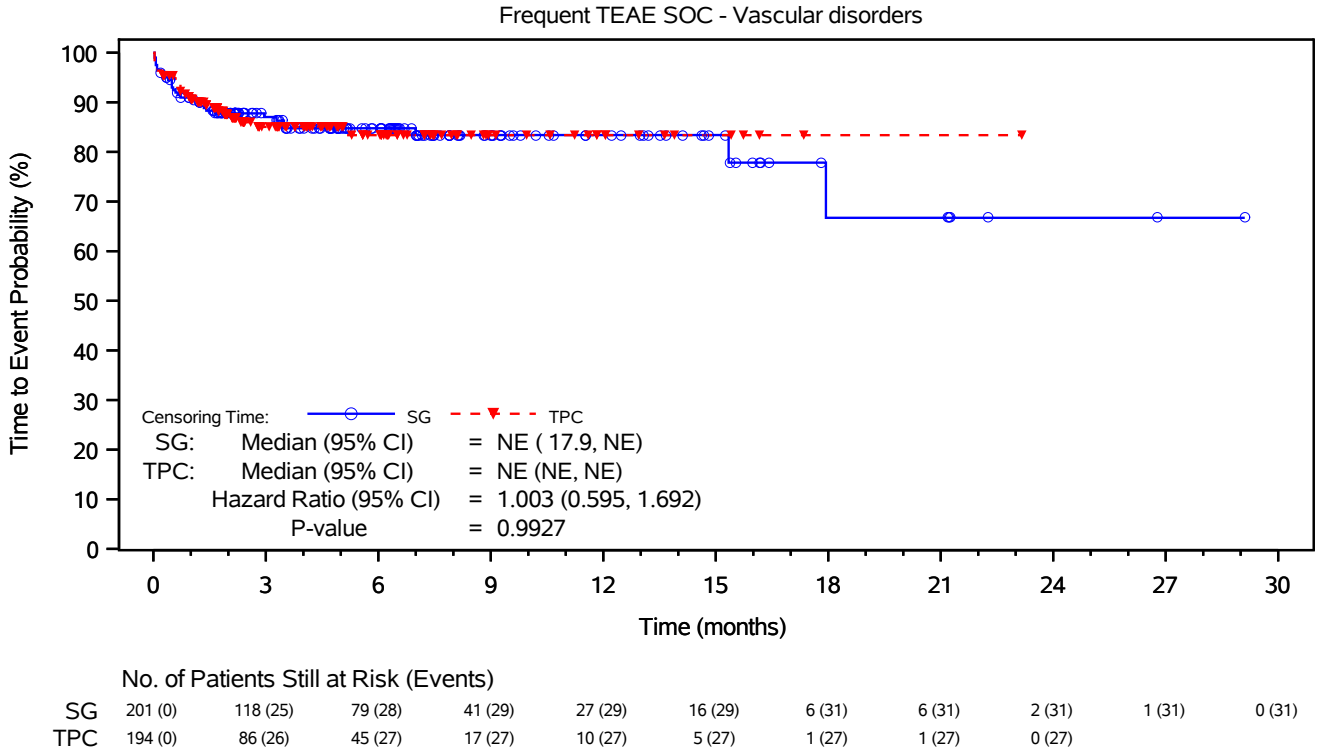

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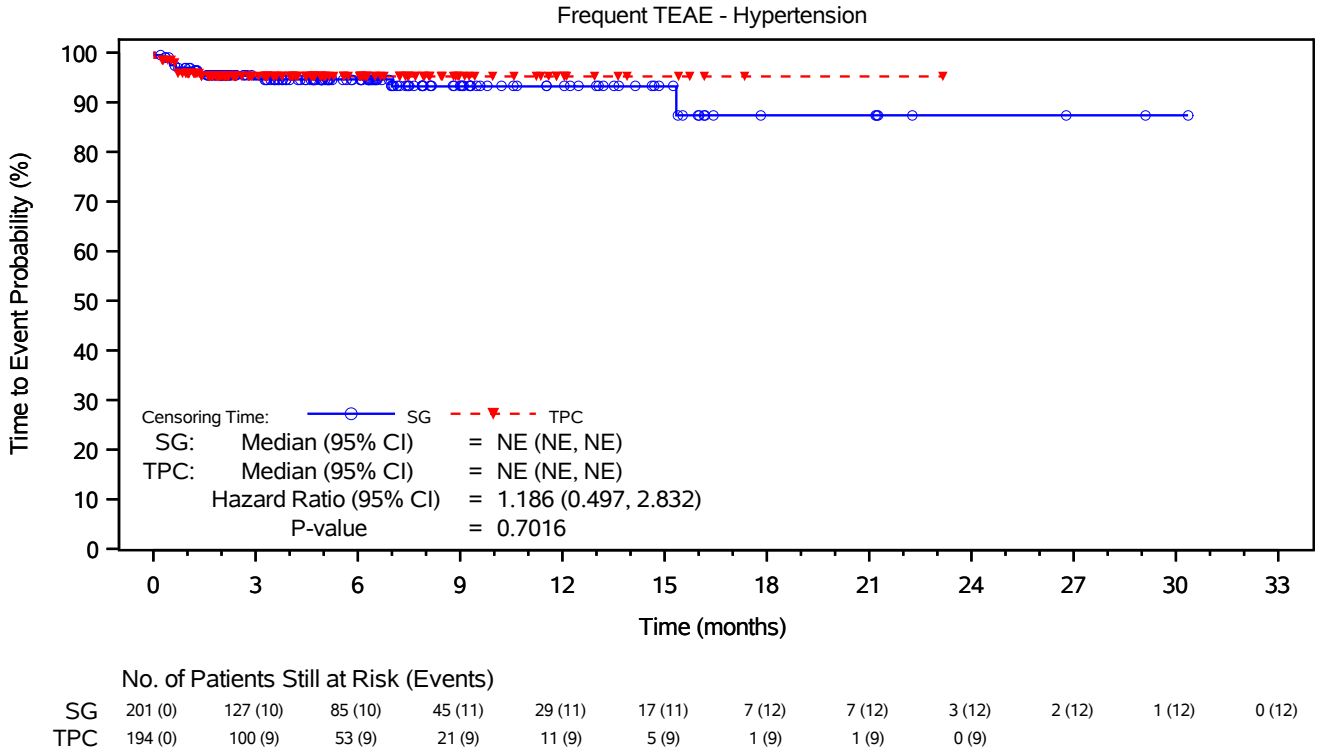

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Table 15.11.7.5: Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Blood and lymphatic system disorders			
Patients With Events (%)	15 (7.5%)	12 (6.2%)	
Patients Without Events (Censored) (%)	186 (92.5%)	182 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.212 (0.567, 2.592)
p-value			0.6203

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.5: Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE - Febrile neutropenia			
Patients With Events (%)	8 (4.0%)	10 (5.2%)	
Patients Without Events (Censored) (%)	193 (96.0%)	184 (94.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.779 (0.307, 1.978)
p-value			0.5977

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
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Table 15.11.7.5: Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Patients With Events (%)	21 (10.4%)	6 (3.1%)	
Patients Without Events (Censored) (%)	180 (89.6%)	188 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.312 (1.335, 8.217)
p-value			0.0062

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.5: Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Infections and infestations			
Patients With Events (%)	19 (9.5%)	8 (4.1%)	
Patients Without Events (Censored) (%)	182 (90.5%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.943 (0.840, 4.494)
p-value			0.1139

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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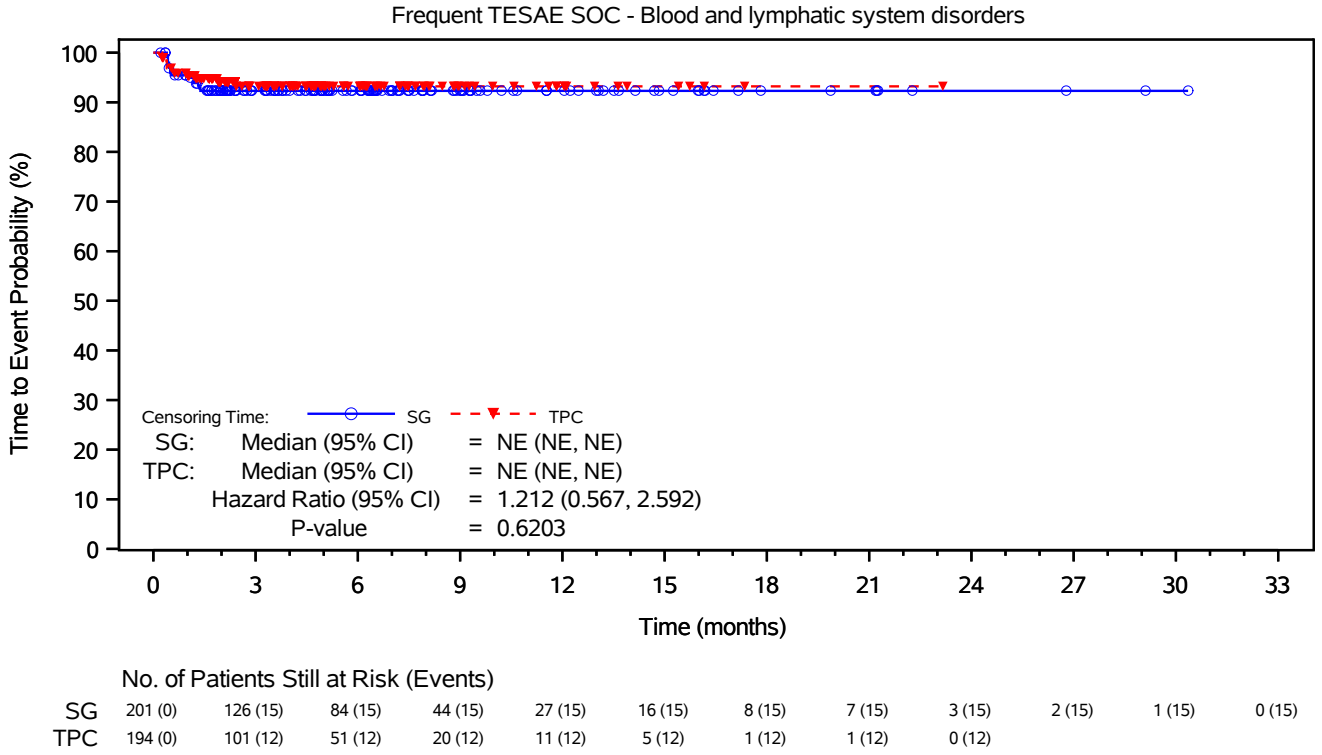
Figure 15.11.7.5: KM Plot for Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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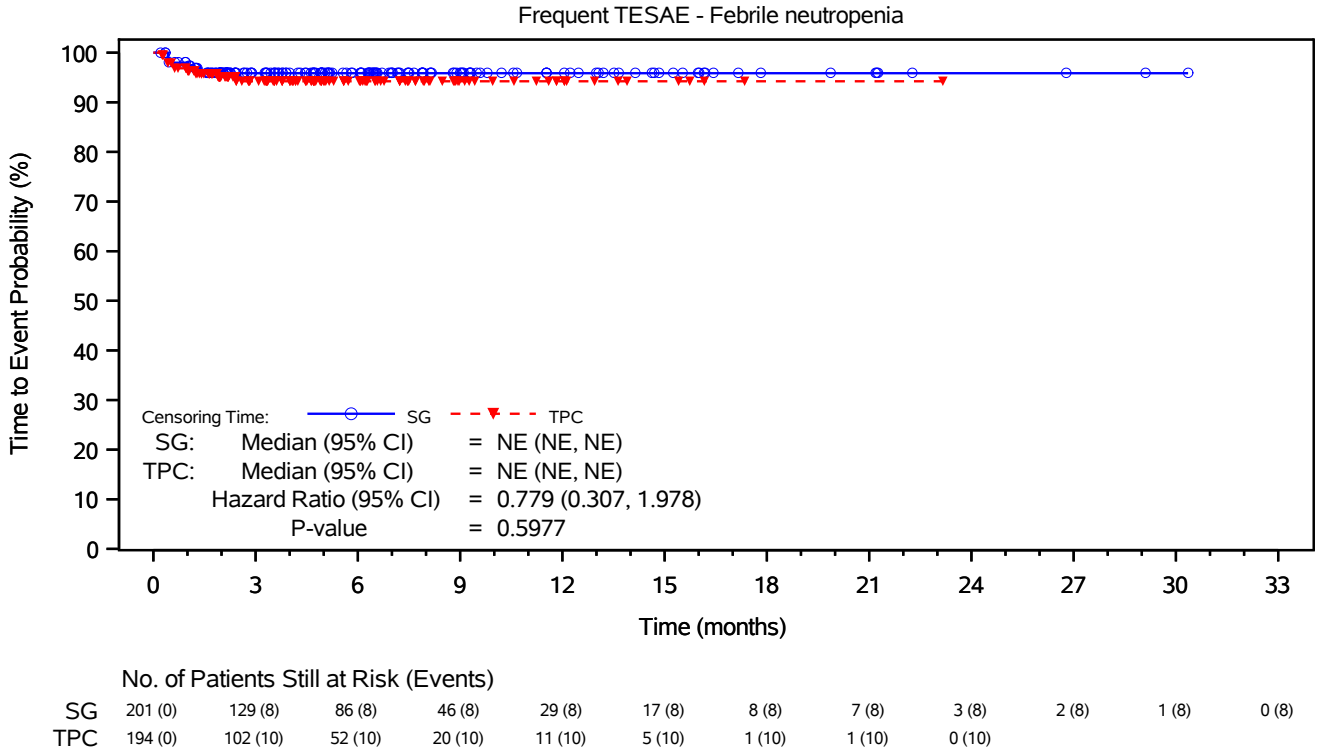
Figure 15.11.7.5: KM Plot for Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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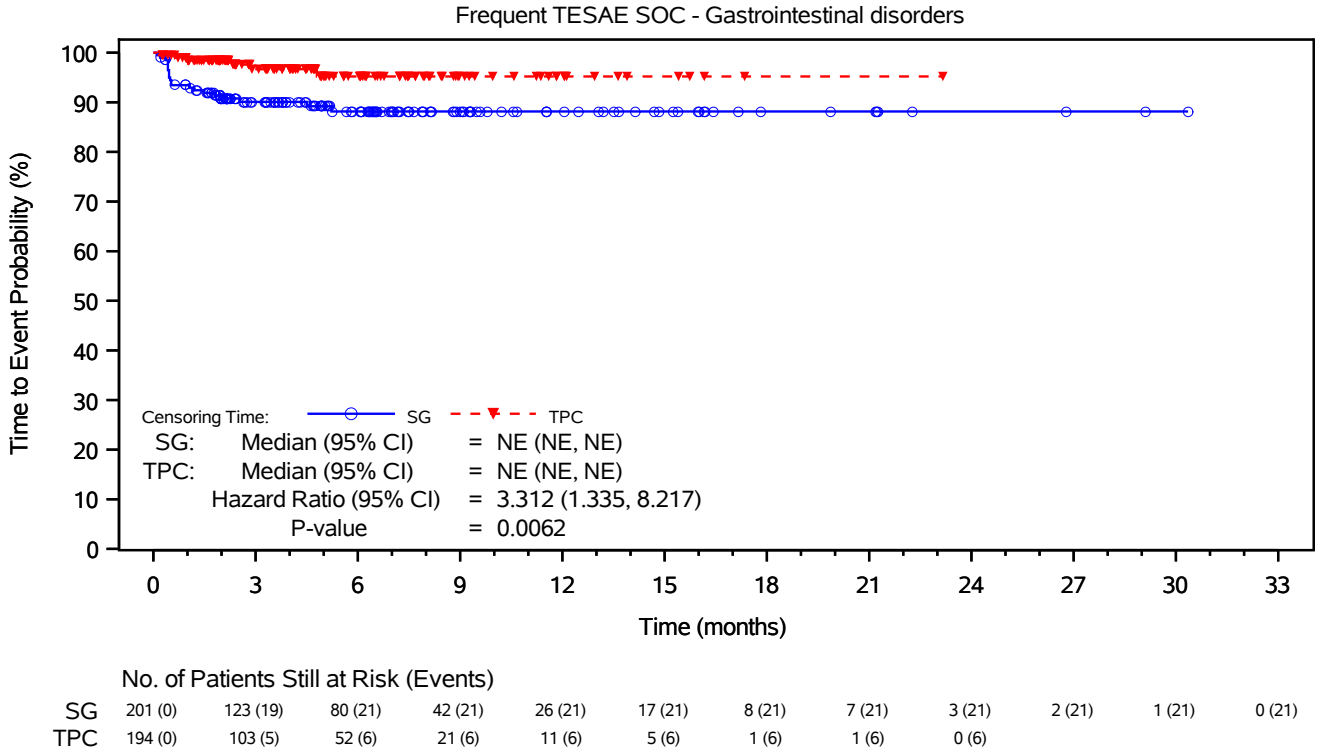
Figure 15.11.7.5: KM Plot for Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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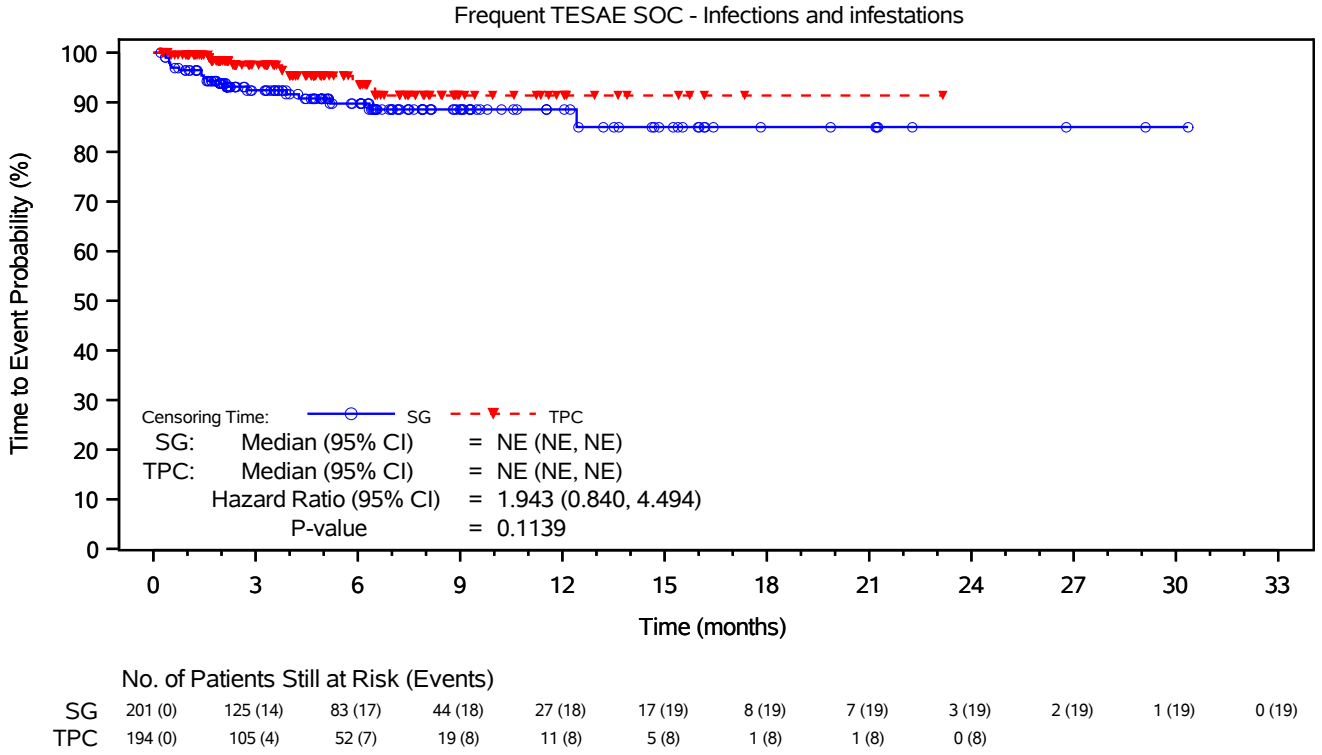
Figure 15.11.7.5: KM Plot for Time to the First Frequent Serious TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Patients With Events (%)	115 (57.2%)	83 (42.8%)	
Patients Without Events (Censored) (%)	86 (42.8%)	111 (57.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.9, 3.0)	8.3 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.485 (1.117, 1.974)
p-value			0.0062

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Patients With Events (%)	16 (8.0%)	5 (2.6%)	
Patients Without Events (Censored) (%)	185 (92.0%)	189 (97.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.883 (1.053, 7.896)
p-value			0.0312

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Febrile neutropenia			
Patients With Events (%)	12 (6.0%)	11 (5.7%)	
Patients Without Events (Censored) (%)	189 (94.0%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.054 (0.464, 2.393)
p-value			0.9016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Leukopenia			
Patients With Events (%)	20 (10.0%)	11 (5.7%)	
Patients Without Events (Censored) (%)	181 (90.0%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.779 (0.852, 3.716)
p-value			0.1220

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Patients With Events (%)	104 (51.7%)	75 (38.7%)	
Patients Without Events (Censored) (%)	97 (48.3%)	119 (61.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (1.0, NE)	9.6 (4.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.436 (1.066, 1.935)
p-value			0.0173

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Patients With Events (%)	31 (15.4%)	11 (5.7%)	
Patients Without Events (Censored) (%)	170 (84.6%)	183 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.628 (1.319, 5.237)
p-value			0.0043

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Patients With Events (%)	19 (9.5%)	3 (1.5%)	
Patients Without Events (Censored) (%)	182 (90.5%)	191 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.953 (1.759, 20.141)
p-value			0.0011

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - General disorders and administration site conditions			
Patients With Events (%)	20 (10.0%)	12 (6.2%)	
Patients Without Events (Censored) (%)	181 (90.0%)	182 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.413 (0.685, 2.916)
p-value			0.3468

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Fatigue			
Patients With Events (%)	12 (6.0%)	6 (3.1%)	
Patients Without Events (Censored) (%)	189 (94.0%)	188 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.822 (0.683, 4.860)
p-value			0.2237

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Infections and infestations			
Patients With Events (%)	21 (10.4%)	8 (4.1%)	
Patients Without Events (Censored) (%)	180 (89.6%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.077 (0.907, 4.756)
p-value			0.0774

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Investigations			
Patients With Events (%)	12 (6.0%)	8 (4.1%)	
Patients Without Events (Censored) (%)	189 (94.0%)	186 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (21.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.241 (0.497, 3.100)
p-value			0.6426

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Metabolism and nutrition disorders			
Patients With Events (%)	17 (8.5%)	6 (3.1%)	
Patients Without Events (Censored) (%)	184 (91.5%)	188 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.436 (0.952, 6.234)
p-value			0.0550

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Patients With Events (%)	7 (3.5%)	14 (7.2%)	
Patients Without Events (Censored) (%)	194 (96.5%)	180 (92.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.322 (0.123, 0.842)
p-value			0.0151

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Patients With Events (%)	11 (5.5%)	17 (8.8%)	
Patients Without Events (Censored) (%)	190 (94.5%)	177 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.463 (0.211, 1.016)
p-value			0.0493

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
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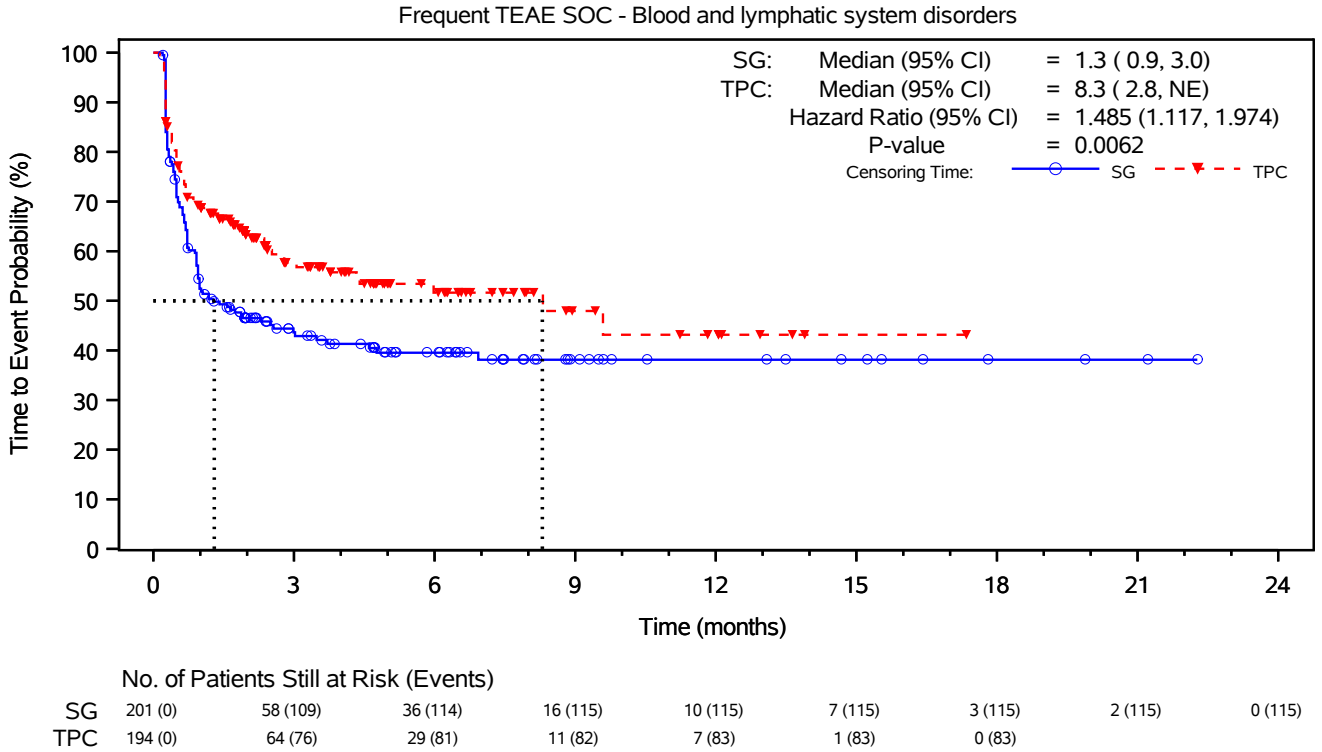
Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

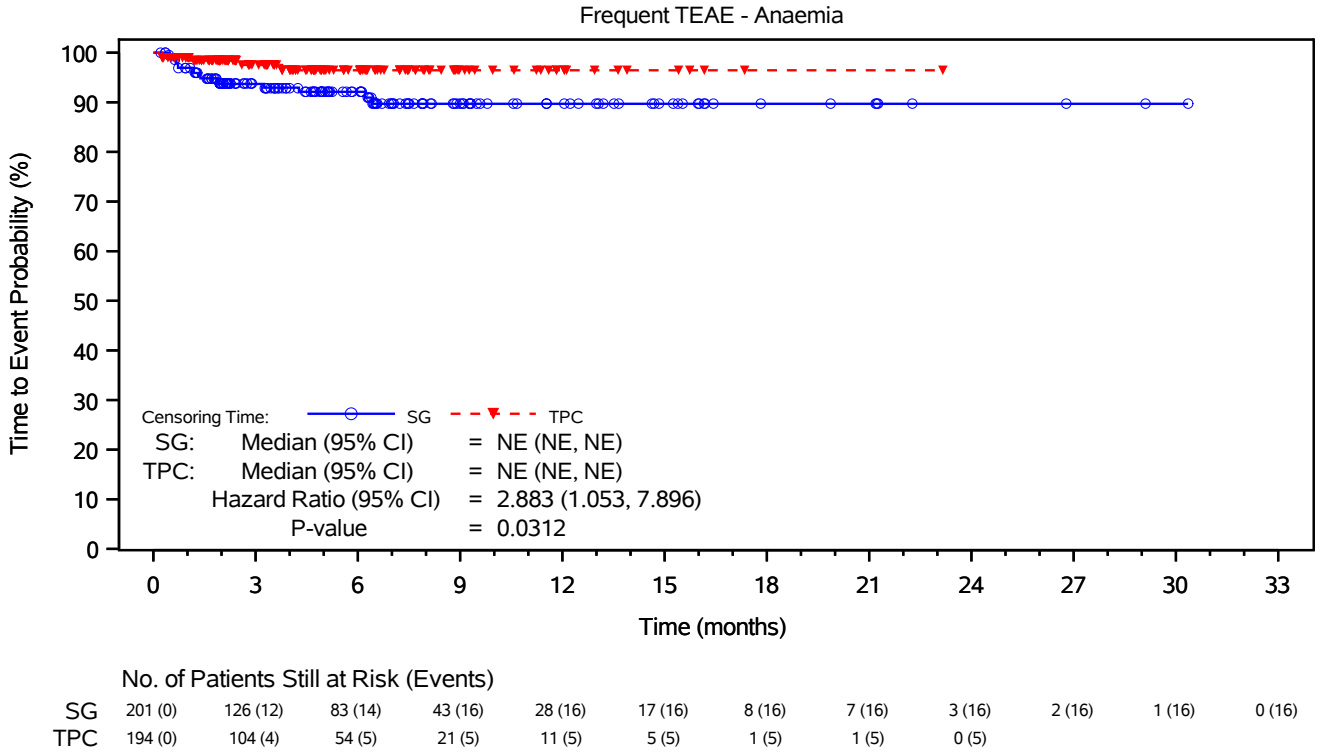

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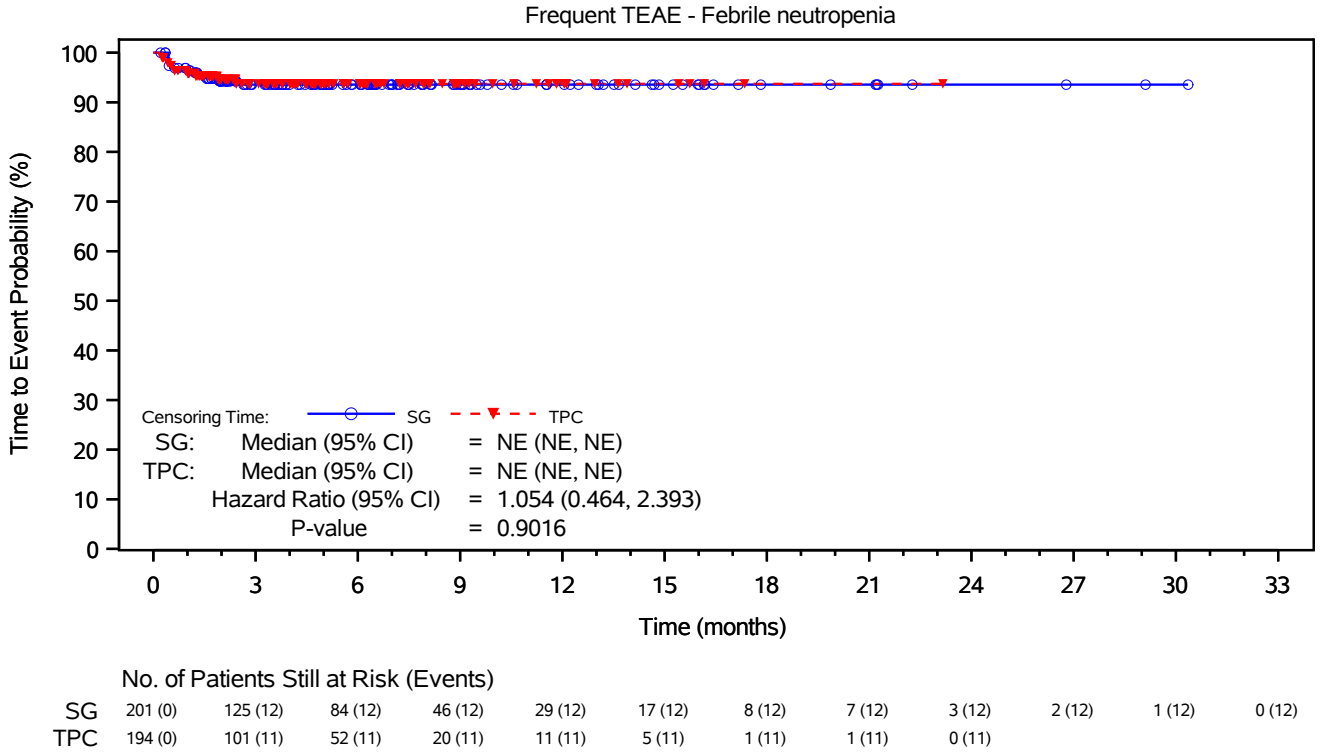
Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



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Hazard ratio and CI are from the stratified Cox regression analysis. P-value is from the stratified log-rank test.

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

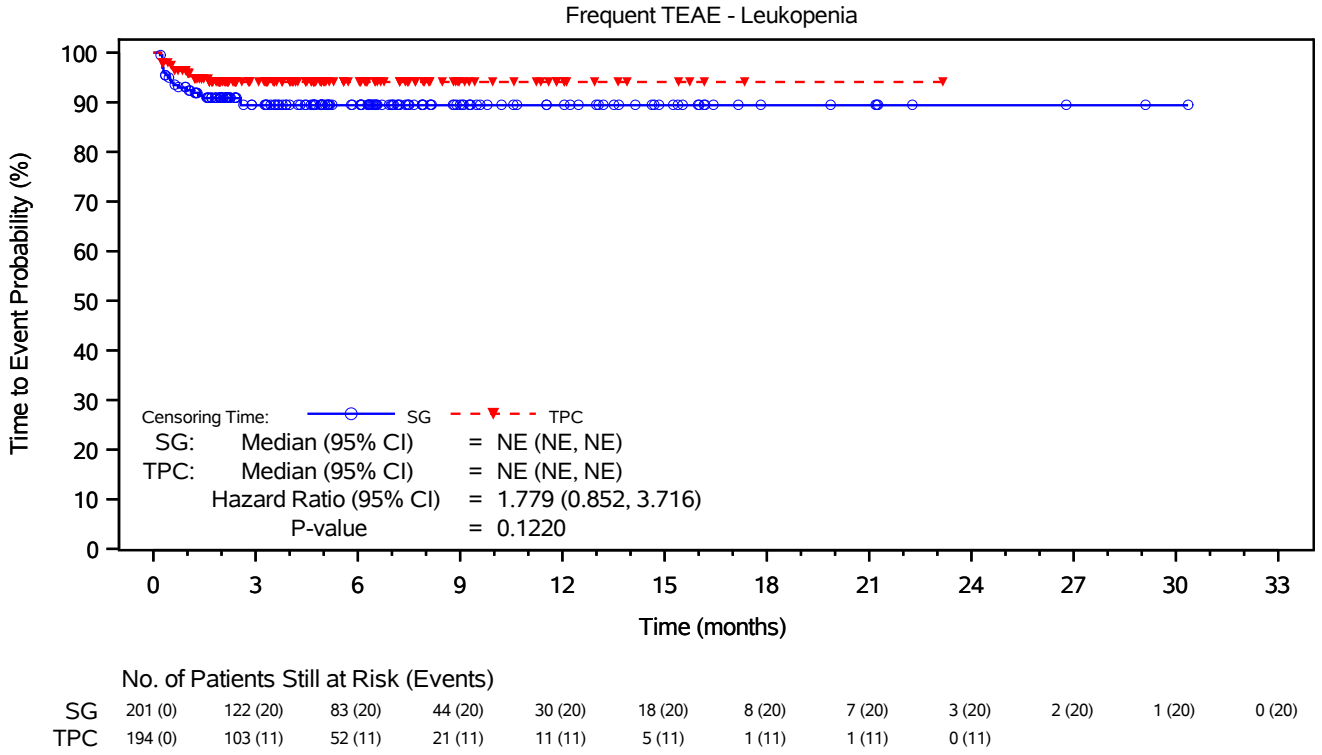

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

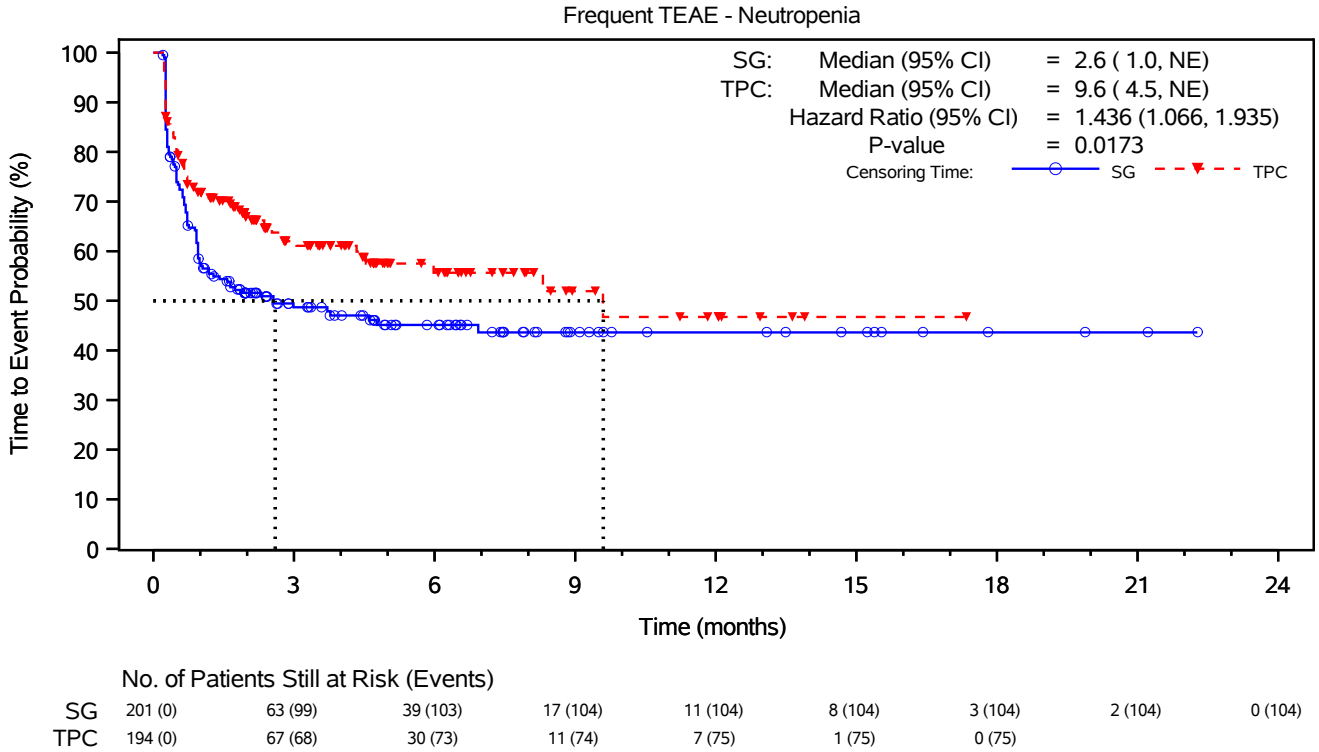

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

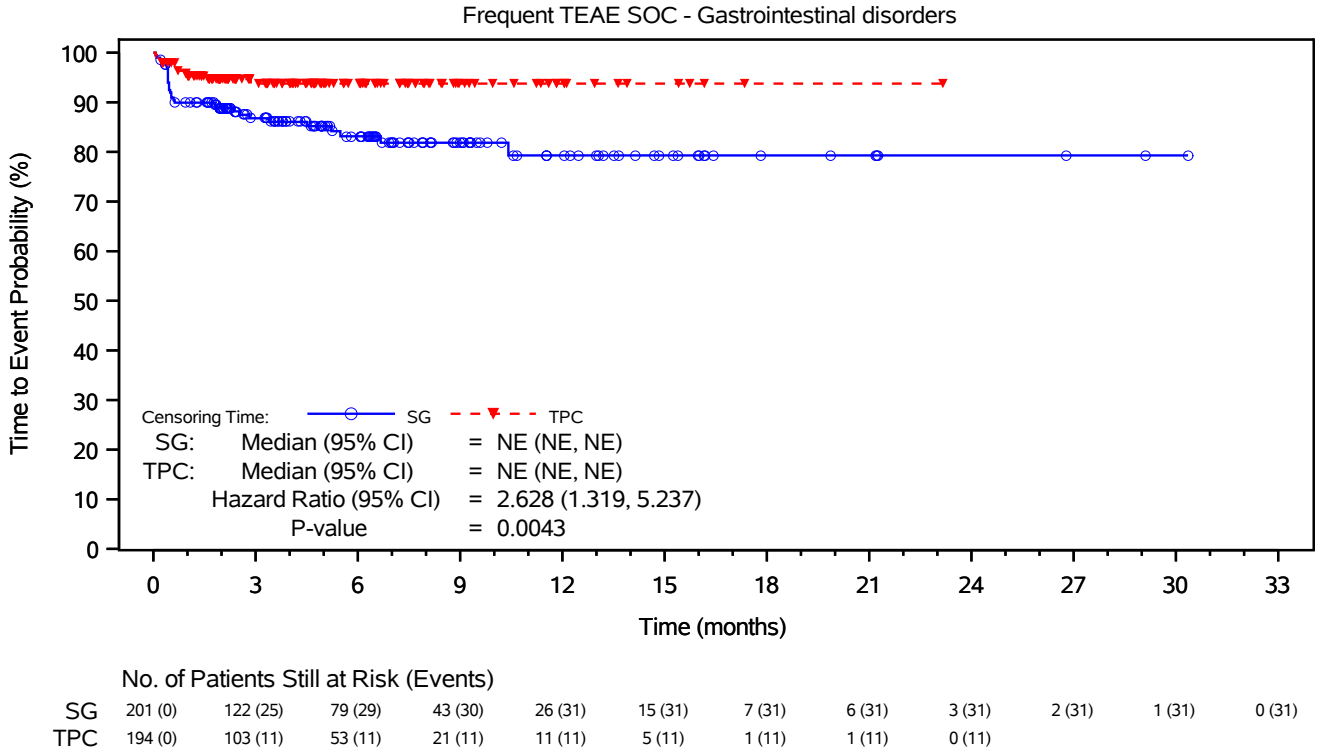

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

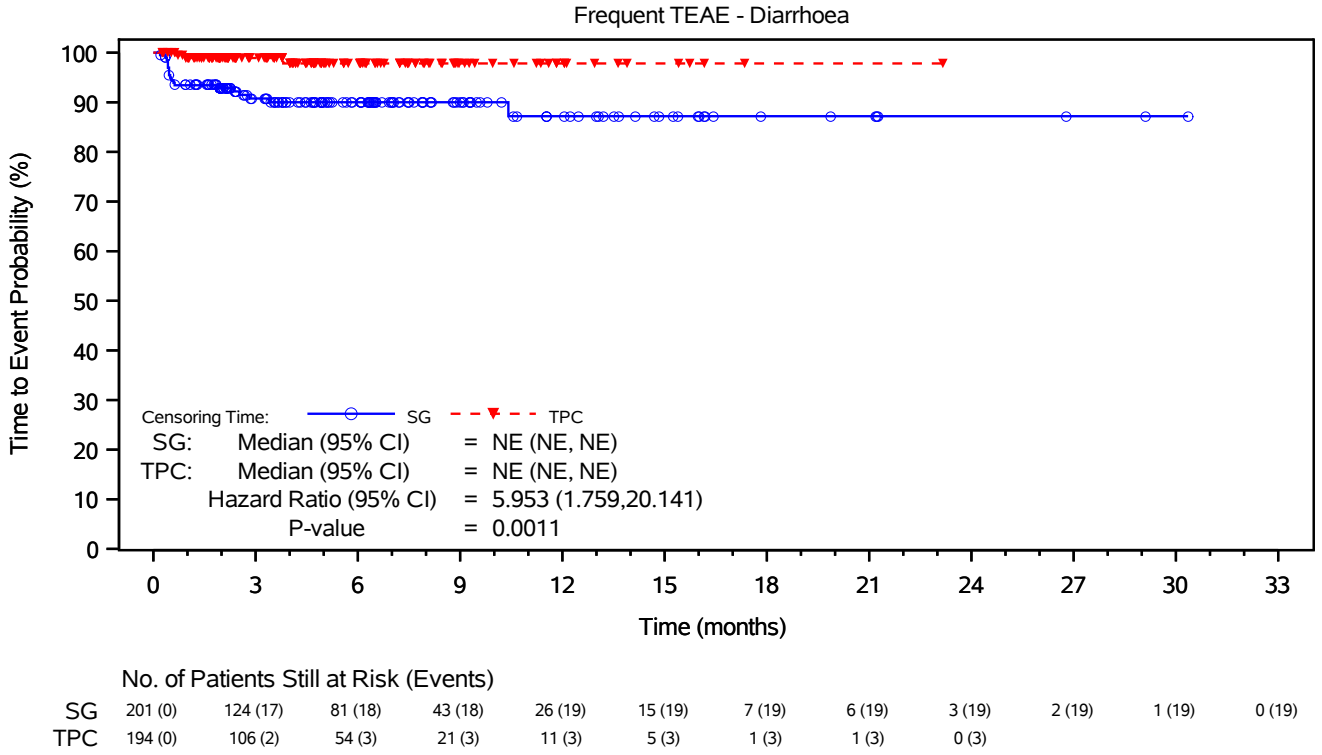

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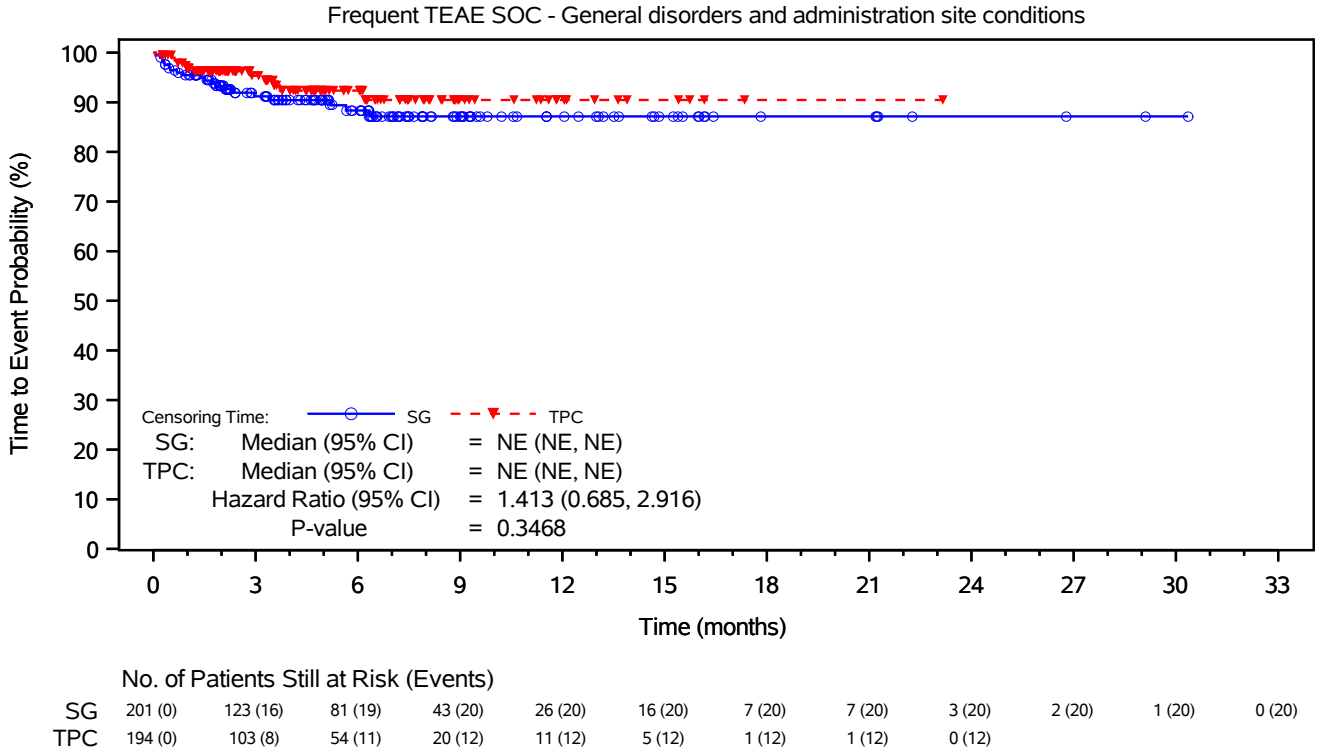
Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine



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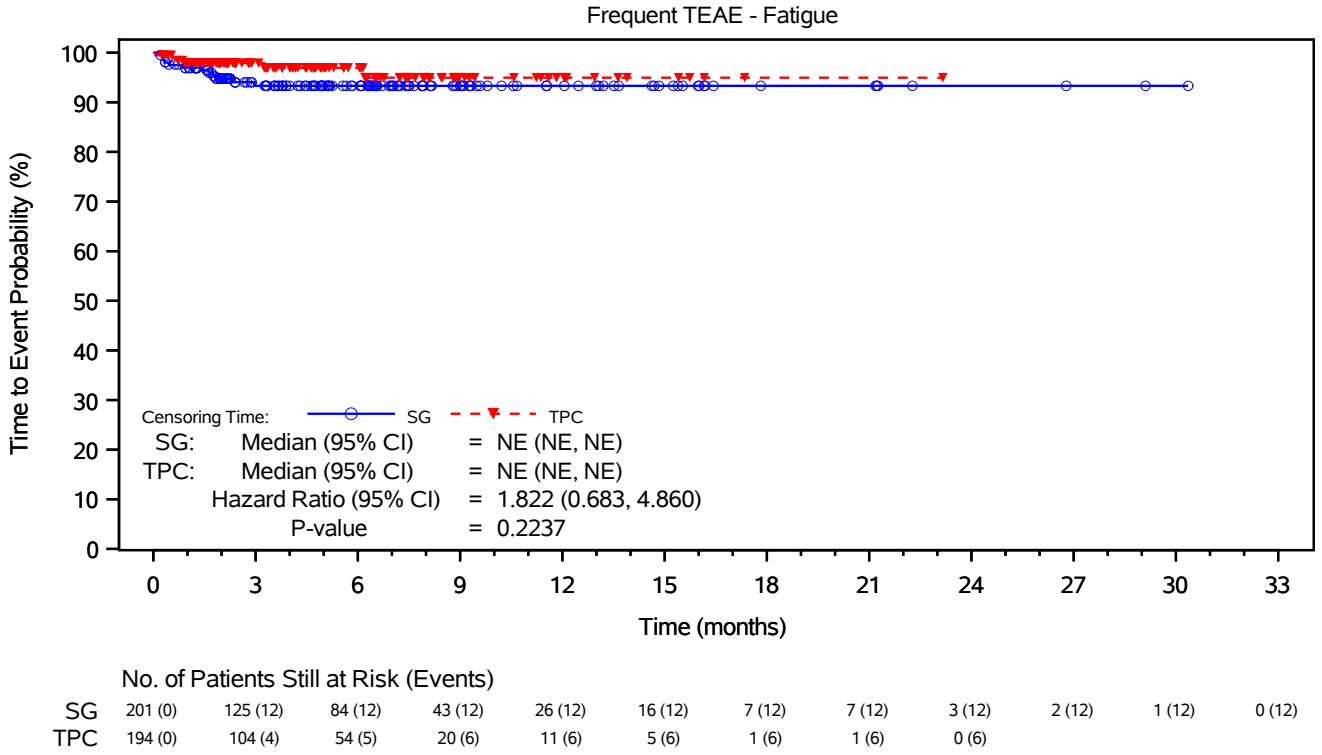
Safety Population
Excluding participants pre-selected to Gemcitabine



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Safety Population
Excluding participants pre-selected to Gemcitabine

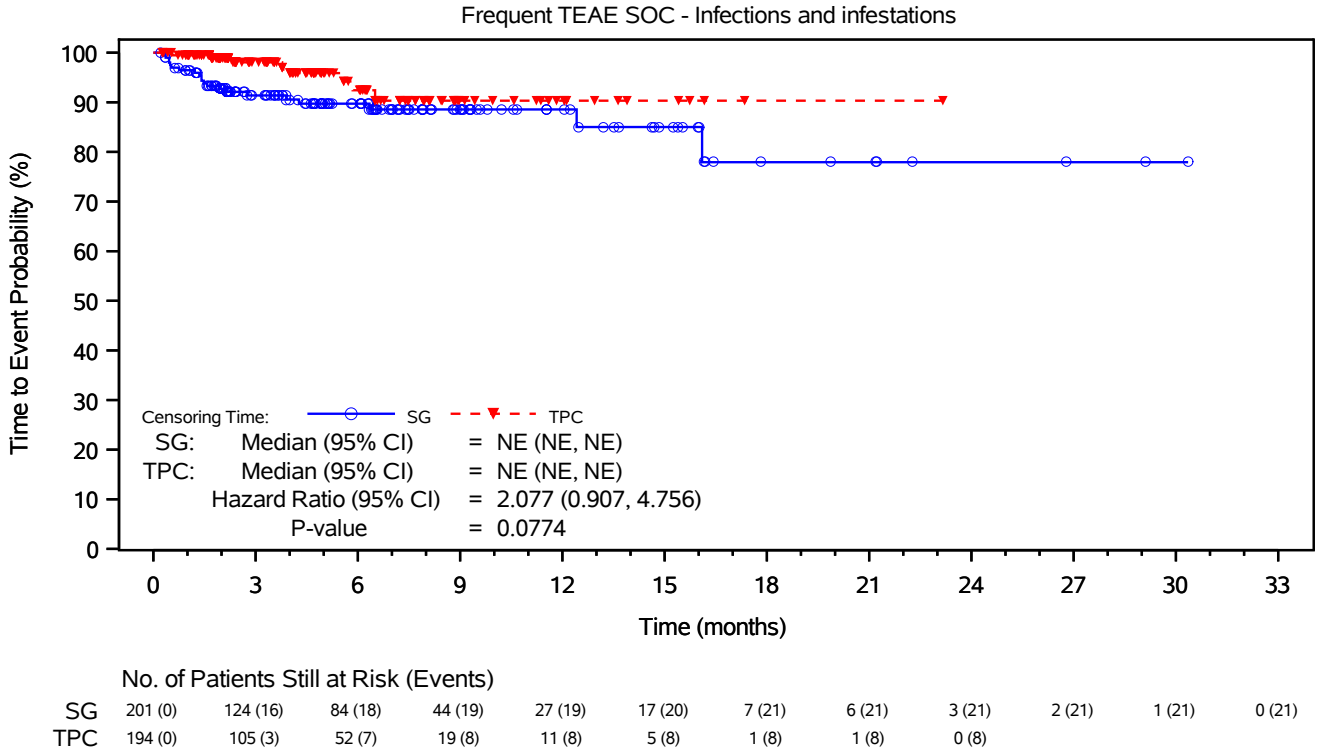

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

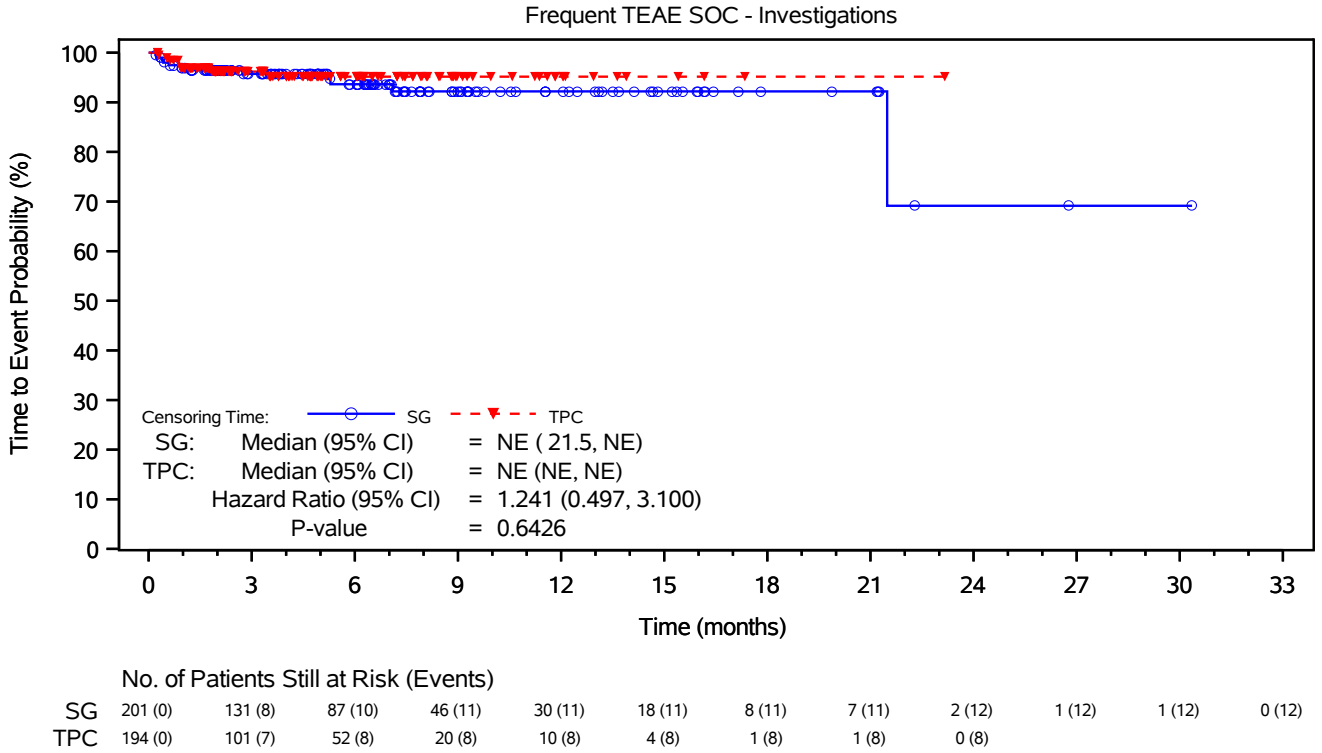

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

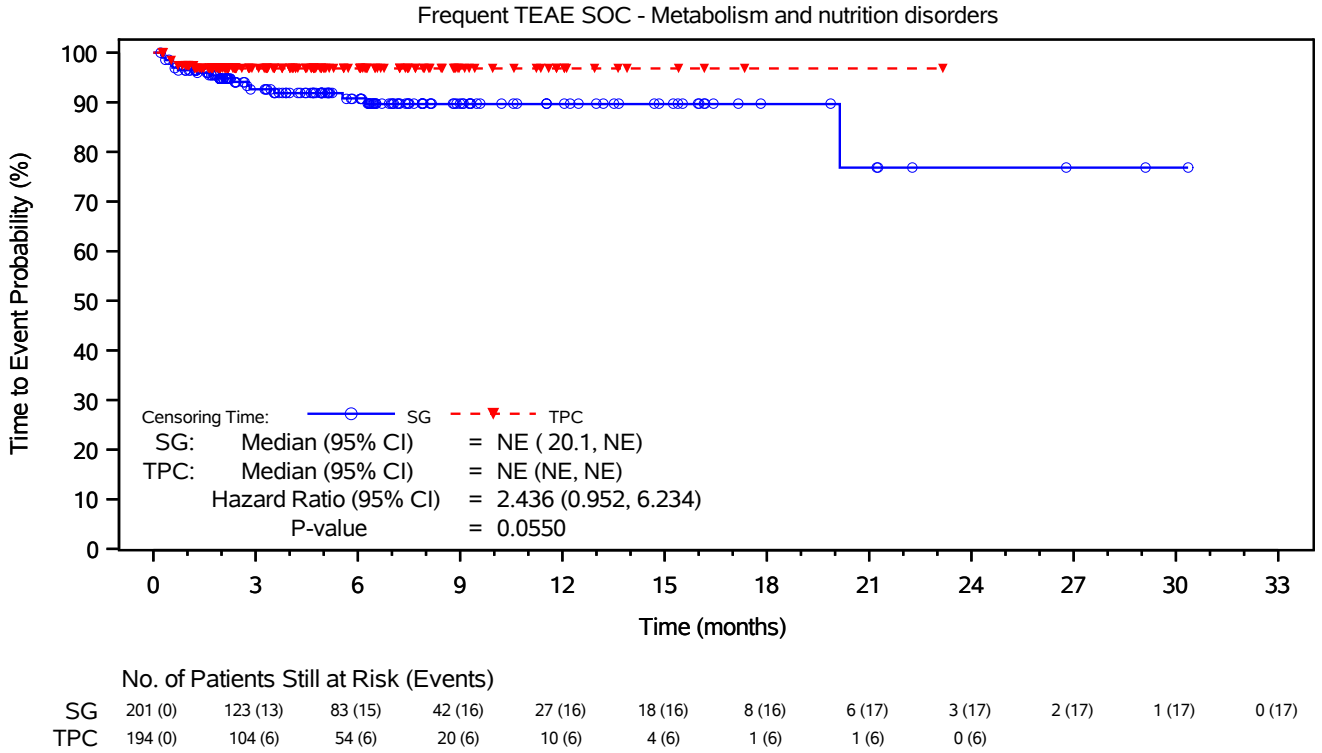

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

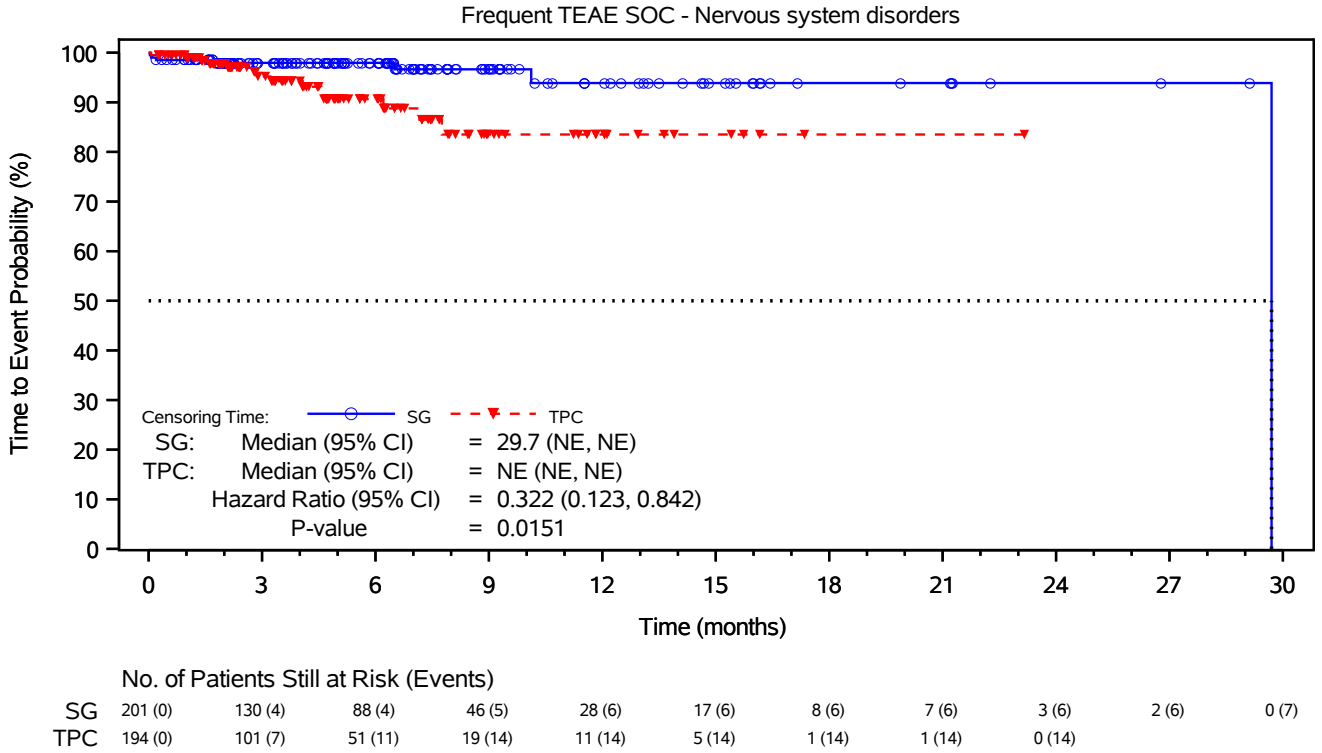

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Figure 15.11.7.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by Selected SOC and PT
Safety Population
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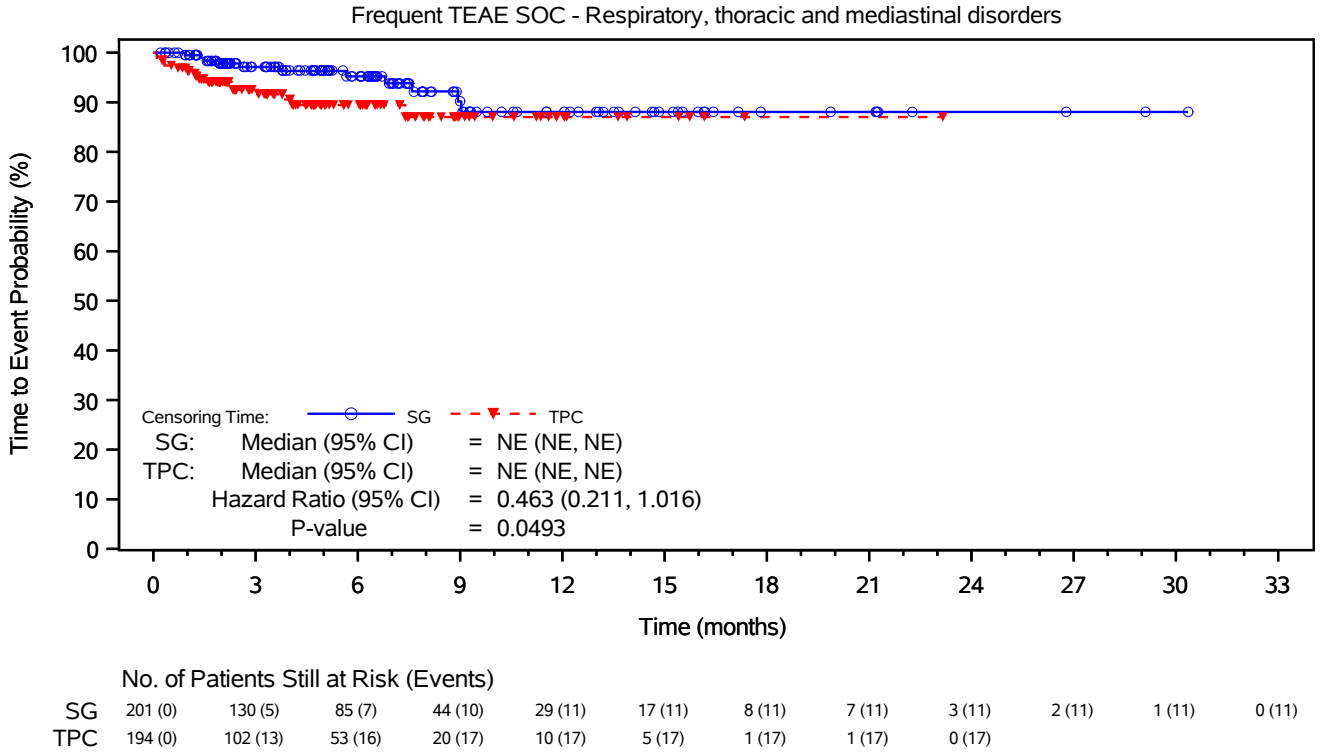

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Table 15.11.8: TEAE Leading to Study Drug Discontinuation by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

System Organ Class Preferred Term	SG (N=201)	TPC (N=194)	Total (N=395)
Subjects with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	14 (7.0%)	6 (3.1%)	20 (5.1%)
Blood and lymphatic system disorders	3 (1.5%)	1 (0.5%)	4 (1.0%)
Neutropenia	2 (1.0%)	0	2 (0.5%)
Anaemia	1 (0.5%)	0	1 (0.3%)
Leukopenia	1 (0.5%)	0	1 (0.3%)
Thrombocytopenia	0	1 (0.5%)	1 (0.3%)
Gastrointestinal disorders	3 (1.5%)	0	3 (0.8%)
Abdominal pain	1 (0.5%)	0	1 (0.3%)
Colitis	1 (0.5%)	0	1 (0.3%)
Neutropenic colitis	1 (0.5%)	0	1 (0.3%)
General disorders and administration site conditions	3 (1.5%)	0	3 (0.8%)
Asthenia	2 (1.0%)	0	2 (0.5%)
General physical health deterioration	1 (0.5%)	0	1 (0.3%)
Hepatobiliary disorders	1 (0.5%)	1 (0.5%)	2 (0.5%)
Hyperbilirubinaemia	1 (0.5%)	1 (0.5%)	2 (0.5%)
Infections and infestations	3 (1.5%)	1 (0.5%)	4 (1.0%)
Pneumonia	1 (0.5%)	1 (0.5%)	2 (0.5%)
COVID-19 pneumonia	1 (0.5%)	0	1 (0.3%)
Diverticulitis	1 (0.5%)	0	1 (0.3%)

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Multiple AEs are counted only once per subejct for each SOC/PT. MedDRA Version 25.0 were used for coding.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
Source: .../germandossier/jan2023/prog/t-aesocpt.sas v9.4 Output file: t-teae-disc-pt-exg.pdf 21APR2023:14:32 Page 1 of 2

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Table 15.11.8: TEAE Leading to Study Drug Discontinuation by SOC and PT
Safety Population
Excluding participants pre-selected to Gemcitabine

System Organ Class Preferred Term	SG (N=201)	TPC (N=194)	Total (N=395)
Subjects with Any Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation	14 (7.0%)	6 (3.1%)	20 (5.1%)
Investigations	1 (0.5%)	0	1 (0.3%)
Alanine aminotransferase increased	1 (0.5%)	0	1 (0.3%)
Aspartate aminotransferase increased	1 (0.5%)	0	1 (0.3%)
Metabolism and nutrition disorders	0	1 (0.5%)	1 (0.3%)
Decreased appetite	0	1 (0.5%)	1 (0.3%)
Musculoskeletal and connective tissue disorders	1 (0.5%)	0	1 (0.3%)
Muscular weakness	1 (0.5%)	0	1 (0.3%)
Nervous system disorders	1 (0.5%)	3 (1.5%)	4 (1.0%)
Polyneuropathy	0	2 (1.0%)	2 (0.5%)
Nervous system disorder	1 (0.5%)	0	1 (0.3%)
Peripheral sensory neuropathy	0	1 (0.5%)	1 (0.3%)
Respiratory, thoracic and mediastinal disorders	1 (0.5%)	0	1 (0.3%)
Pleural effusion	1 (0.5%)	0	1 (0.3%)

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
Multiple AEs are counted only once per subejct for each SOC/PT. MedDRA Version 25.0 were used for coding.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
Source: .../germandossier/jan2023/prog/t-aesocpt.sas v9.4 Output file: t-teae-disc-pt-exg.pdf 21APR2023:14:32 Page 2 of 2

Anhang 4-G 7.5: Subgruppenanalysen

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9352
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	95 (100.0%)	89 (96.7%)	
Patients (%) Without Events (Censored)	0	3 (3.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.537 (1.142, 2.070)
p-value			0.0047
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	106 (100.0%)	96 (94.1%)	
Patients (%) Without Events (Censored)	0	6 (5.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.545 (1.163, 2.053)
p-value			0.0031

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.6203
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	192 (100.0%)	177 (95.2%)	
Patients (%) Without Events (Censored)	0	9 (4.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.520 (1.232, 1.874)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	9 (100.0%)	8 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.0, 0.3)	0.2 (0.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.250 (0.742, 6.828)
p-value			0.1430

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.7772
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	180 (100.0%)	163 (95.3%)	
Patients (%) Without Events (Censored)	0	8 (4.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.535 (1.234, 1.909)
p-value			0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	21 (100.0%)	22 (95.7%)	
Patients (%) Without Events (Censored)	0	1 (4.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.0, 0.1)	0.1 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.764 (0.945, 3.293)
p-value			0.0773

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.5780
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	155 (100.0%)	138 (93.9%)	
Patients (%) Without Events (Censored)	0	9 (6.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.478 (1.168, 1.870)
p-value			0.0012
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	46 (100.0%)	47 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.970 (1.274, 3.046)
p-value			0.0021

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.5511
Race: White			
Total Patients	141	132	
Patients (%) With Events	141 (100.0%)	125 (94.7%)	
Patients (%) Without Events (Censored)	0	7 (5.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.522 (1.187, 1.951)
p-value			0.0008
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	13 (100.0%)	16 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.0, 0.3)	0.2 (0.1, 0.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.281 (1.037, 5.017)
p-value			0.0461

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9353
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	87 (100.0%)	86 (95.6%)	
Patients (%) Without Events (Censored)	0	4 (4.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.511 (1.112, 2.054)
p-value			0.0081
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	114 (100.0%)	99 (95.2%)	
Patients (%) Without Events (Censored)	0	5 (4.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.557 (1.181, 2.052)
p-value			0.0018

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9620
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	123 (100.0%)	115 (95.0%)	
Patients (%) Without Events (Censored)	0	6 (5.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.520 (1.170, 1.975)
p-value			0.0018
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	78 (100.0%)	70 (95.9%)	
Patients (%) Without Events (Censored)	0	3 (4.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.702 (1.212, 2.390)
p-value			0.0020

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.1545
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	116 (100.0%)	113 (95.0%)	
Patients (%) Without Events (Censored)	0	6 (5.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.391 (1.069, 1.811)
p-value			0.0168
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	80 (100.0%)	70 (95.9%)	
Patients (%) Without Events (Censored)	0	3 (4.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.821 (1.300, 2.551)
p-value			0.0004

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.0033
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	21 (100.0%)	23 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.0, 0.1)	0.1 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.660 (1.783, 7.514)
p-value			0.0002
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	126 (100.0%)	112 (93.3%)	
Patients (%) Without Events (Censored)	0	8 (6.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.575 (1.210, 2.049)
p-value			0.0006
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	
Patients (%) With Events	54 (100.0%)	50 (98.0%)	
Patients (%) Without Events (Censored)	0	1 (2.0%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.227 (0.831, 1.814)
p-value			0.3252

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9310
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	13 (100.0%)	13 (92.9%)	
Patients (%) Without Events (Censored)	0	1 (7.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.2 (0.1, NE)	0.1 (0.0, 0.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.923 (0.778, 4.753)
p-value			0.2417
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	181 (100.0%)	168 (95.5%)	
Patients (%) Without Events (Censored)	0	8 (4.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.531 (1.234, 1.899)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.4873
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	177 (100.0%)	162 (94.7%)	
Patients (%) Without Events (Censored)	0	9 (5.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.576 (1.264, 1.964)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	24 (100.0%)	23 (100.0%)	
Patients (%) Without Events (Censored)	0	0	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.360 (0.754, 2.452)
p-value			0.3838

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.2713
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	122 (100.0%)	121 (93.8%)	
Patients (%) Without Events (Censored)	0	8 (6.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.682 (1.296, 2.185)
p-value			0.0001
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	79 (100.0%)	64 (98.5%)	
Patients (%) Without Events (Censored)	0	1 (1.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.340 (0.958, 1.875)
p-value			0.0847

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.4239
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	68 (100.0%)	70 (97.2%)	
Patients (%) Without Events (Censored)	0	2 (2.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.2 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.457 (1.038, 2.044)
p-value			0.0281
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	71 (100.0%)	70 (94.6%)	
Patients (%) Without Events (Censored)	0	4 (5.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.1)	0.2 (0.1, 0.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.605 (1.140, 2.262)
p-value			0.0084
Trop2: H-Score > 200			
Total Patients	40	26	
Patients (%) With Events	40 (100.0%)	25 (96.2%)	
Patients (%) Without Events (Censored)	0	1 (3.8%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.1.2: Time to the First Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.1, 0.2)	0.1 (0.1, 0.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.187 (0.707, 1.994)
p-value			0.5344

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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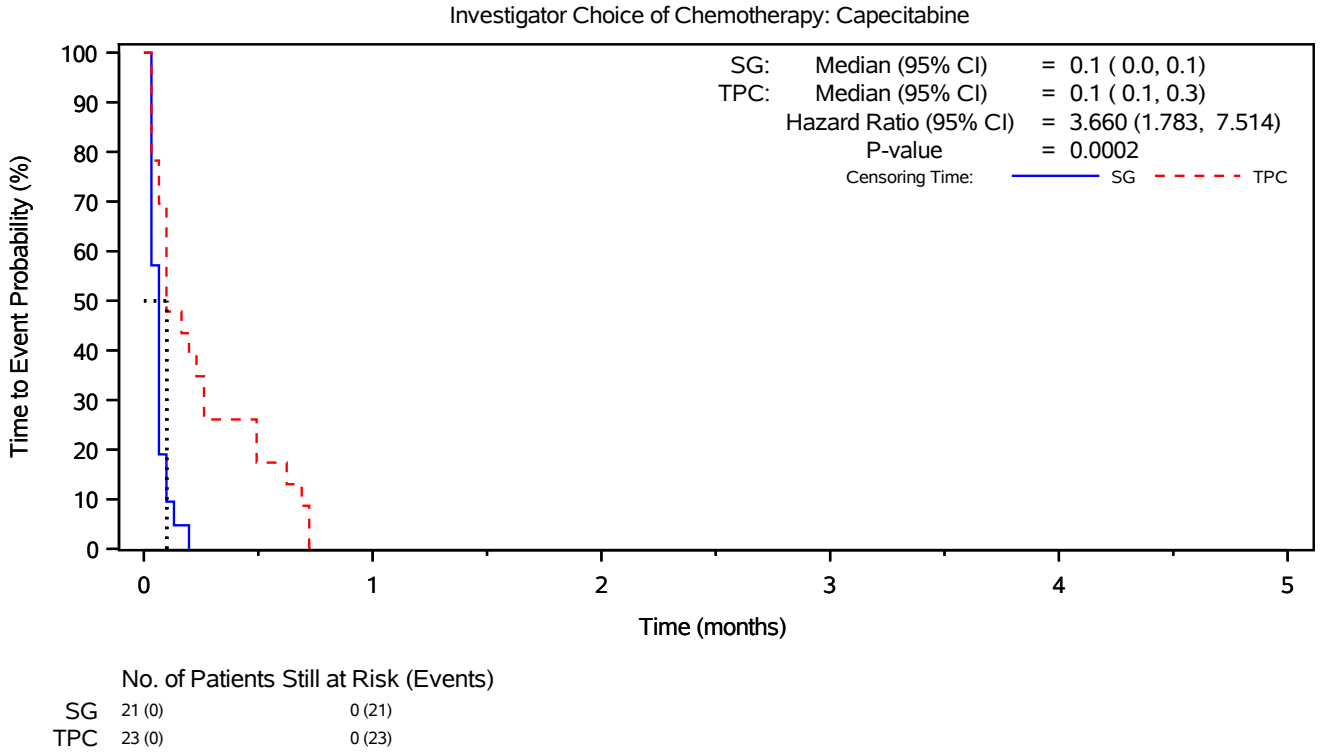
Figure 15.11.2.1.2: KM Plot for Time to the First TEAE by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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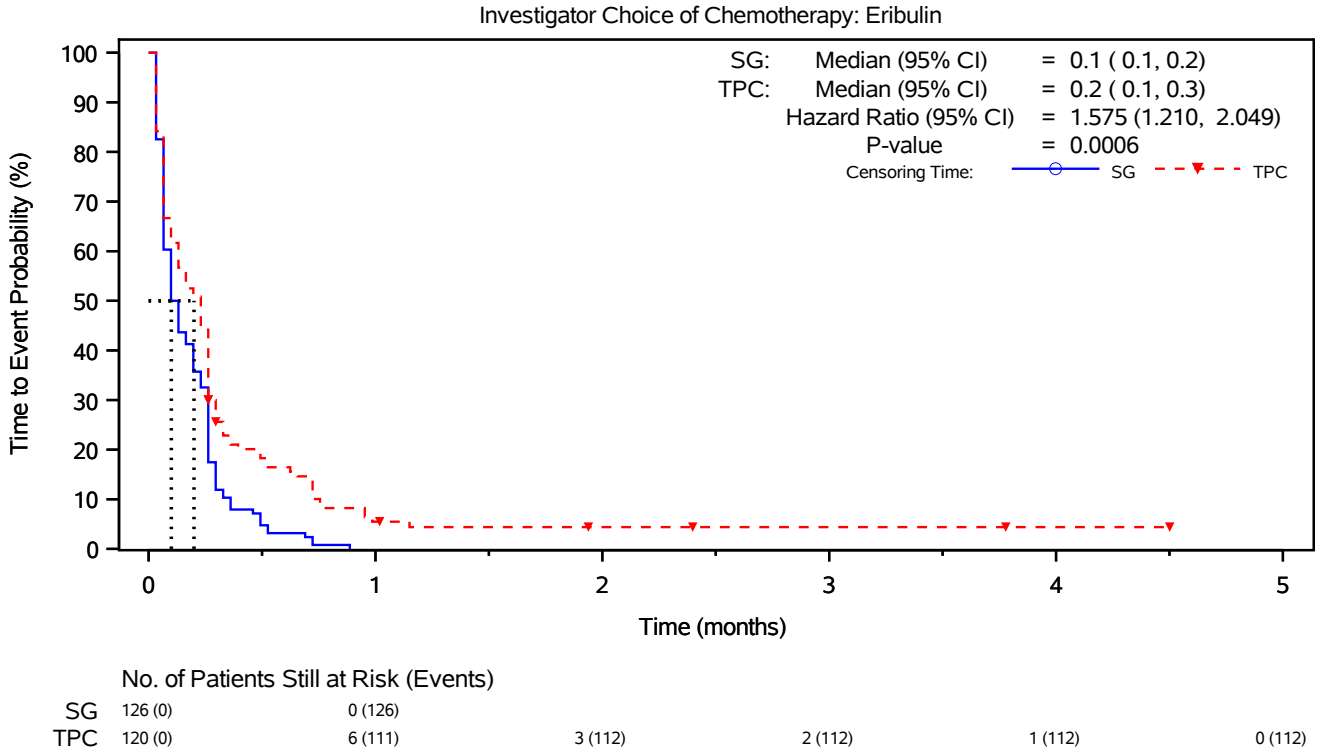
Figure 15.11.2.1.2: KM Plot for Time to the First TEAE by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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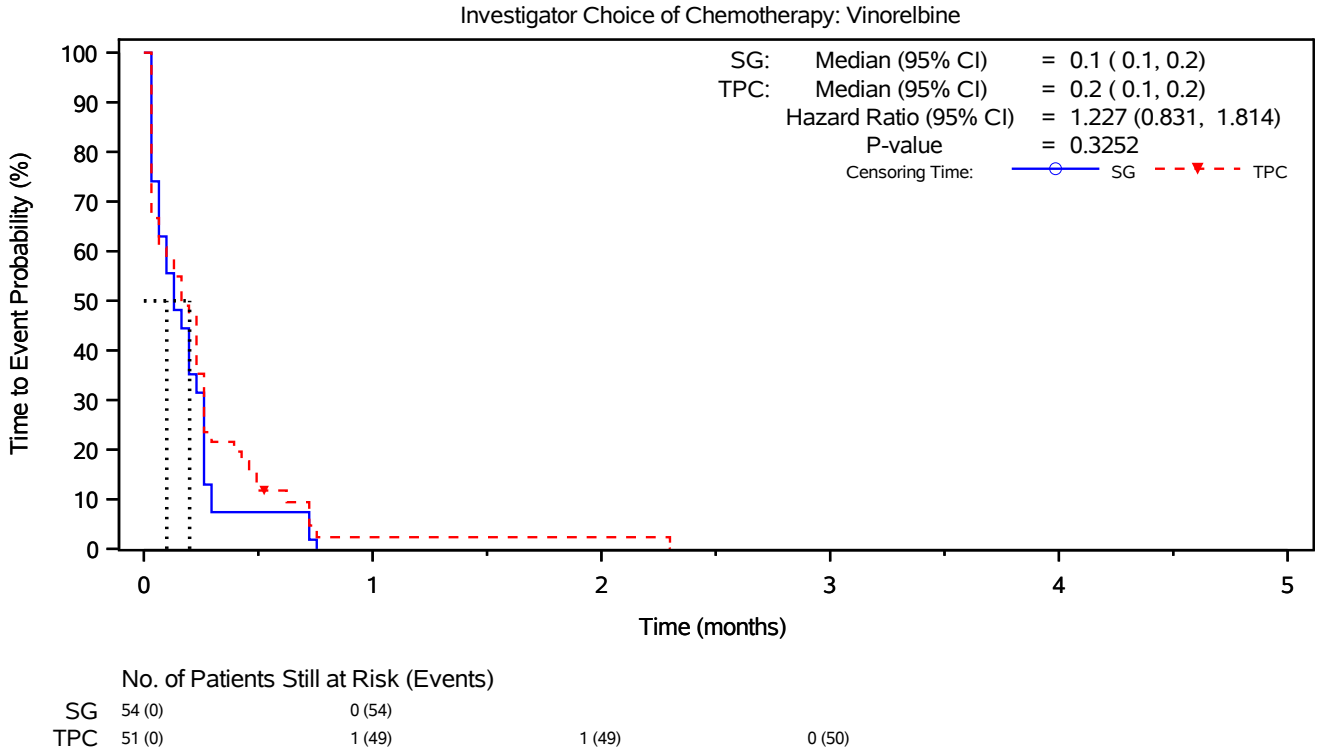
Figure 15.11.2.1.2: KM Plot for Time to the First TEAE by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



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NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9152
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	26 (27.4%)	17 (18.5%)	
Patients (%) Without Events (Censored)	69 (72.6%)	75 (81.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (10.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.387 (0.752, 2.558)
p-value			0.2954
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	29 (27.4%)	17 (16.7%)	
Patients (%) Without Events (Censored)	77 (72.6%)	85 (83.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	17.9 (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.453 (0.794, 2.660)
p-value			0.2217

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9796
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	53 (27.6%)	34 (18.3%)	
Patients (%) Without Events (Censored)	139 (72.4%)	152 (81.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.379 (0.895, 2.126)
p-value			0.1434
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	2 (22.2%)	0	
Patients (%) Without Events (Censored)	7 (77.8%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2416

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.3920
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	49 (27.2%)	28 (16.4%)	
Patients (%) Without Events (Censored)	131 (72.8%)	143 (83.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.529 (0.959, 2.437)
p-value			0.0719
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	6 (28.6%)	6 (26.1%)	
Patients (%) Without Events (Censored)	15 (71.4%)	17 (73.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.7, NE)	NE (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.892 (0.279, 2.848)
p-value			0.8464

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.1134
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	35 (22.6%)	25 (17.0%)	
Patients (%) Without Events (Censored)	120 (77.4%)	122 (83.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.172 (0.700, 1.964)
p-value			0.5445
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	20 (43.5%)	9 (19.1%)	
Patients (%) Without Events (Censored)	26 (56.5%)	38 (80.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	17.9 (2.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.382 (1.082, 5.241)
p-value			0.0261

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.8856
Race: White			
Total Patients	141	132	
Patients (%) With Events	43 (30.5%)	26 (19.7%)	
Patients (%) Without Events (Censored)	98 (69.5%)	106 (80.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	17.9 (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.368 (0.837, 2.236)
p-value			0.2094
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	1 (6.3%)	
Patients (%) Without Events (Censored)	12 (92.3%)	15 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.110 (0.069, 17.806)
p-value			0.9415

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.3946
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	20 (23.0%)	16 (17.8%)	
Patients (%) Without Events (Censored)	67 (77.0%)	74 (82.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.117 (0.575, 2.168)
p-value			0.7460
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	35 (30.7%)	18 (17.3%)	
Patients (%) Without Events (Censored)	79 (69.3%)	86 (82.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.688 (0.955, 2.982)
p-value			0.0678

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.1981
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	36 (29.3%)	19 (15.7%)	
Patients (%) Without Events (Censored)	87 (70.7%)	102 (84.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.807 (1.035, 3.154)
p-value			0.0348
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	19 (24.4%)	15 (20.5%)	
Patients (%) Without Events (Censored)	59 (75.6%)	58 (79.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	17.9 (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.944 (0.475, 1.876)
p-value			0.8706

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.6029
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	31 (26.7%)	17 (14.3%)	
Patients (%) Without Events (Censored)	85 (73.3%)	102 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.723 (0.951, 3.123)
p-value			0.0704
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	24 (30.0%)	16 (21.9%)	
Patients (%) Without Events (Censored)	56 (70.0%)	57 (78.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	17.9 (6.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.295 (0.687, 2.443)
p-value			0.4220

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.7822
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	5 (23.8%)	3 (13.0%)	
Patients (%) Without Events (Censored)	16 (76.2%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (4.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.691 (0.404, 7.083)
p-value			0.4675
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	37 (29.4%)	24 (20.0%)	
Patients (%) Without Events (Censored)	89 (70.6%)	96 (80.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	17.9 (10.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.424 (0.850, 2.383)
p-value			0.1771
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	
Patients (%) With Events	13 (24.1%)	7 (13.7%)	
Patients (%) Without Events (Censored)	41 (75.9%)	44 (86.3%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.412 (0.560, 3.562)
p-value			0.4637

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.0952
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	3 (21.4%)	
Patients (%) Without Events (Censored)	12 (92.3%)	11 (78.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (1.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.146 (0.013, 1.700)
p-value			0.0911
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	51 (28.2%)	30 (17.0%)	
Patients (%) Without Events (Censored)	130 (71.8%)	146 (83.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.551 (0.986, 2.438)
p-value			0.0557

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.7918
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	47 (26.6%)	30 (17.5%)	
Patients (%) Without Events (Censored)	130 (73.4%)	141 (82.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.398 (0.882, 2.214)
p-value			0.1525
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	8 (33.3%)	4 (17.4%)	
Patients (%) Without Events (Censored)	16 (66.7%)	19 (82.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.7, NE)	NE (5.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.576 (0.473, 5.254)
p-value			0.4549

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.6962
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	33 (27.0%)	23 (17.8%)	
Patients (%) Without Events (Censored)	89 (73.0%)	106 (82.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (17.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.346 (0.786, 2.305)
p-value			0.2779
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	22 (27.8%)	11 (16.9%)	
Patients (%) Without Events (Censored)	57 (72.2%)	54 (83.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.569 (0.760, 3.238)
p-value			0.2191

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.7738
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	18 (26.5%)	12 (16.7%)	
Patients (%) Without Events (Censored)	50 (73.5%)	60 (83.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.603 (0.771, 3.334)
p-value			0.2041
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	20 (28.2%)	14 (18.9%)	
Patients (%) Without Events (Censored)	51 (71.8%)	60 (81.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.219 (0.611, 2.430)
p-value			0.5725
Trop2: H-Score > 200			
Total Patients	40	26	
Patients (%) With Events	13 (32.5%)	6 (23.1%)	
Patients (%) Without Events (Censored)	27 (67.5%)	20 (76.9%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.2.2: Time to the First Serious Treatment-Emergent Adverse Event (SAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	17.9 (10.2, NE)	NE (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.262 (0.473, 3.363)
p-value			0.6400

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.3681
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	72 (75.8%)	48 (52.2%)	
Patients (%) Without Events (Censored)	23 (24.2%)	44 (47.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.5, 1.6)	2.9 (1.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.663 (1.154, 2.398)
p-value			0.0055
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	79 (74.5%)	62 (60.8%)	
Patients (%) Without Events (Censored)	27 (25.5%)	40 (39.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.6, 1.0)	1.9 (0.7, 3.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.341 (0.961, 1.872)
p-value			0.0864

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.7983
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	144 (75.0%)	105 (56.5%)	
Patients (%) Without Events (Censored)	48 (25.0%)	81 (43.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 1.0)	2.4 (1.0, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.477 (1.148, 1.900)
p-value			0.0023
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	7 (77.8%)	5 (62.5%)	
Patients (%) Without Events (Censored)	2 (22.2%)	3 (37.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.2, NE)	4.5 (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.483 (0.718, 8.589)
p-value			0.1379

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.3299
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	137 (76.1%)	96 (56.1%)	
Patients (%) Without Events (Censored)	43 (23.9%)	75 (43.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.6, 1.0)	2.6 (1.2, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.549 (1.193, 2.012)
p-value			0.0010
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	14 (66.7%)	14 (60.9%)	
Patients (%) Without Events (Censored)	7 (33.3%)	9 (39.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.4, NE)	1.7 (0.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.022 (0.486, 2.149)
p-value			0.9474

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.2531
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	114 (73.5%)	84 (57.1%)	
Patients (%) Without Events (Censored)	41 (26.5%)	63 (42.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.6, 1.2)	2.1 (0.9, 3.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.371 (1.034, 1.818)
p-value			0.0284
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	37 (80.4%)	26 (55.3%)	
Patients (%) Without Events (Censored)	9 (19.6%)	21 (44.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 1.0)	3.7 (0.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.919 (1.156, 3.187)
p-value			0.0106

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.5717
Race: White			
Total Patients	141	132	
Patients (%) With Events	109 (77.3%)	79 (59.8%)	
Patients (%) Without Events (Censored)	32 (22.7%)	53 (40.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 1.0)	2.1 (0.9, 3.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.467 (1.097, 1.961)
p-value			0.0097
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	8 (61.5%)	9 (56.3%)	
Patients (%) Without Events (Censored)	5 (38.5%)	7 (43.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.3, NE)	0.7 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.148 (0.442, 2.981)
p-value			0.8104

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.1818
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	59 (67.8%)	51 (56.7%)	
Patients (%) Without Events (Censored)	28 (32.2%)	39 (43.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.6, 1.9)	2.9 (1.0, 7.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.212 (0.832, 1.765)
p-value			0.3183
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	92 (80.7%)	59 (56.7%)	
Patients (%) Without Events (Censored)	22 (19.3%)	45 (43.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 1.0)	2.1 (0.7, 3.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.723 (1.241, 2.390)
p-value			0.0010

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.5056
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	90 (73.2%)	69 (57.0%)	
Patients (%) Without Events (Censored)	33 (26.8%)	52 (43.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 1.2)	2.3 (1.0, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.392 (1.017, 1.906)
p-value			0.0365
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	61 (78.2%)	41 (56.2%)	
Patients (%) Without Events (Censored)	17 (21.8%)	32 (43.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 1.0)	2.4 (0.7, 7.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.635 (1.100, 2.431)
p-value			0.0161

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.4184
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	86 (74.1%)	66 (55.5%)	
Patients (%) Without Events (Censored)	30 (25.9%)	53 (44.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.6, 1.6)	2.4 (0.9, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.397 (1.013, 1.926)
p-value			0.0363
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	63 (78.8%)	43 (58.9%)	
Patients (%) Without Events (Censored)	17 (21.3%)	30 (41.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.4, 1.0)	2.6 (0.9, 5.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.746 (1.183, 2.577)
p-value			0.0054

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.0188
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	17 (81.0%)	7 (30.4%)	
Patients (%) Without Events (Censored)	4 (19.0%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.4, 3.0)	NE (7.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.917 (1.603, 9.572)
p-value			0.0013
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	92 (73.0%)	70 (58.3%)	
Patients (%) Without Events (Censored)	34 (27.0%)	50 (41.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 1.2)	2.4 (1.2, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.402 (1.027, 1.915)
p-value			0.0301
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	
Patients (%) With Events	42 (77.8%)	33 (64.7%)	
Patients (%) Without Events (Censored)	12 (22.2%)	18 (35.3%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.5, 1.0)	0.9 (0.5, 2.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.154 (0.727, 1.830)
p-value			0.5747

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.4871
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	8 (61.5%)	7 (50.0%)	
Patients (%) Without Events (Censored)	5 (38.5%)	7 (50.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.3, NE)	0.9 (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.014 (0.354, 2.900)
p-value			0.9879
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	138 (76.2%)	101 (57.4%)	
Patients (%) Without Events (Censored)	43 (23.8%)	75 (42.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 1.0)	2.3 (1.1, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.524 (1.179, 1.971)
p-value			0.0012

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9132
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	132 (74.6%)	96 (56.1%)	
Patients (%) Without Events (Censored)	45 (25.4%)	75 (43.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 1.0)	2.4 (1.0, 3.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.490 (1.145, 1.939)
p-value			0.0028
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	19 (79.2%)	14 (60.9%)	
Patients (%) Without Events (Censored)	5 (20.8%)	9 (39.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.5 (0.6, 3.7)	5.0 (0.7, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.419 (0.711, 2.833)
p-value			0.3212

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9678
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	92 (75.4%)	73 (56.6%)	
Patients (%) Without Events (Censored)	30 (24.6%)	56 (43.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.6, 1.0)	2.4 (0.9, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.505 (1.107, 2.048)
p-value			0.0087
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	59 (74.7%)	37 (56.9%)	
Patients (%) Without Events (Censored)	20 (25.3%)	28 (43.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 1.3)	2.7 (0.7, 9.6)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.461 (0.968, 2.206)
p-value			0.0692

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.7104
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	54 (79.4%)	42 (58.3%)	
Patients (%) Without Events (Censored)	14 (20.6%)	30 (41.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.4, 1.0)	1.1 (0.7, 7.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.732 (1.155, 2.597)
p-value			0.0069
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	51 (71.8%)	43 (58.1%)	
Patients (%) Without Events (Censored)	20 (28.2%)	31 (41.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, 2.8)	2.4 (0.7, 5.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.092 (0.725, 1.646)
p-value			0.6804
Trop2: H-Score > 200			
Total Patients	40	26	
Patients (%) With Events	31 (77.5%)	17 (65.4%)	
Patients (%) Without Events (Censored)	9 (22.5%)	9 (34.6%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.2.3.2: Time to the First Grade 3 or Higher Treatment-Emergent Adverse Event (TEAE) by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, 0.9)	2.1 (0.6, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.547 (0.854, 2.804)
p-value			0.1458

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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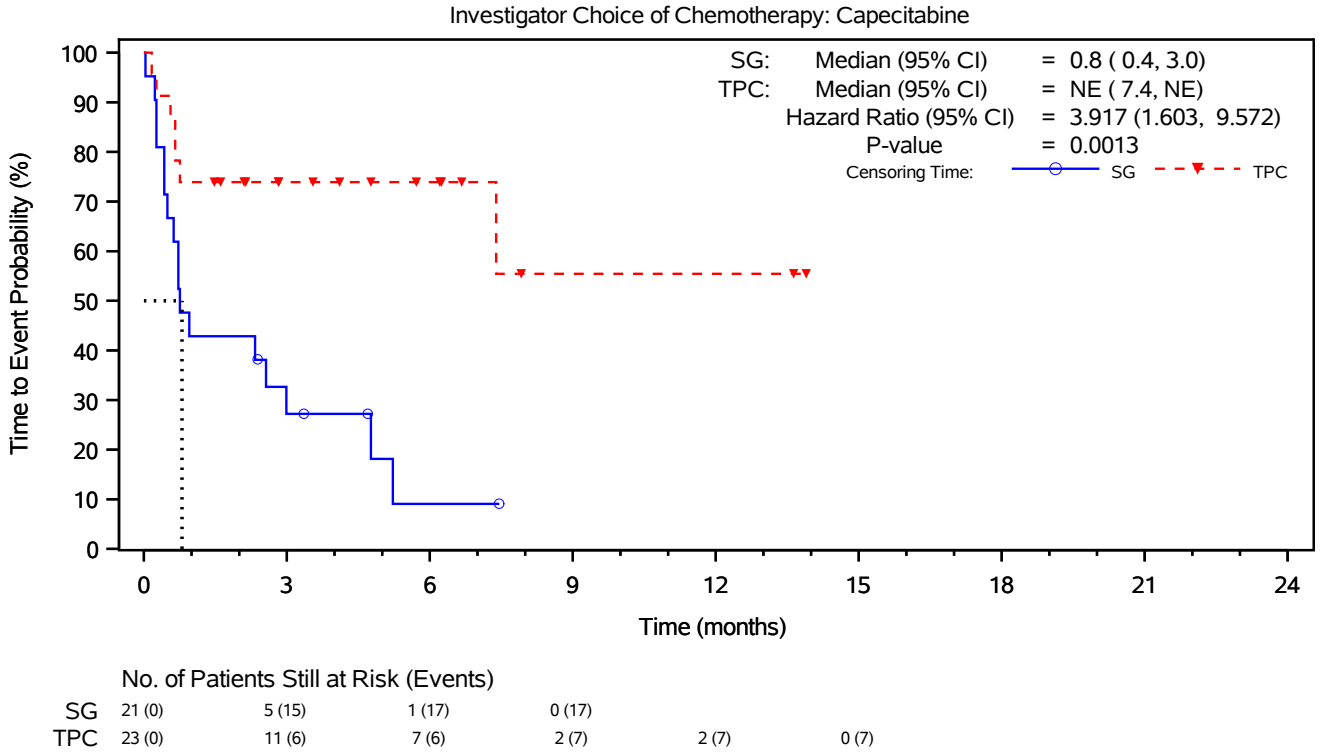
Figure 15.11.2.3.2: KM Plot for Time to the First Grade 3 or Higher TEAE by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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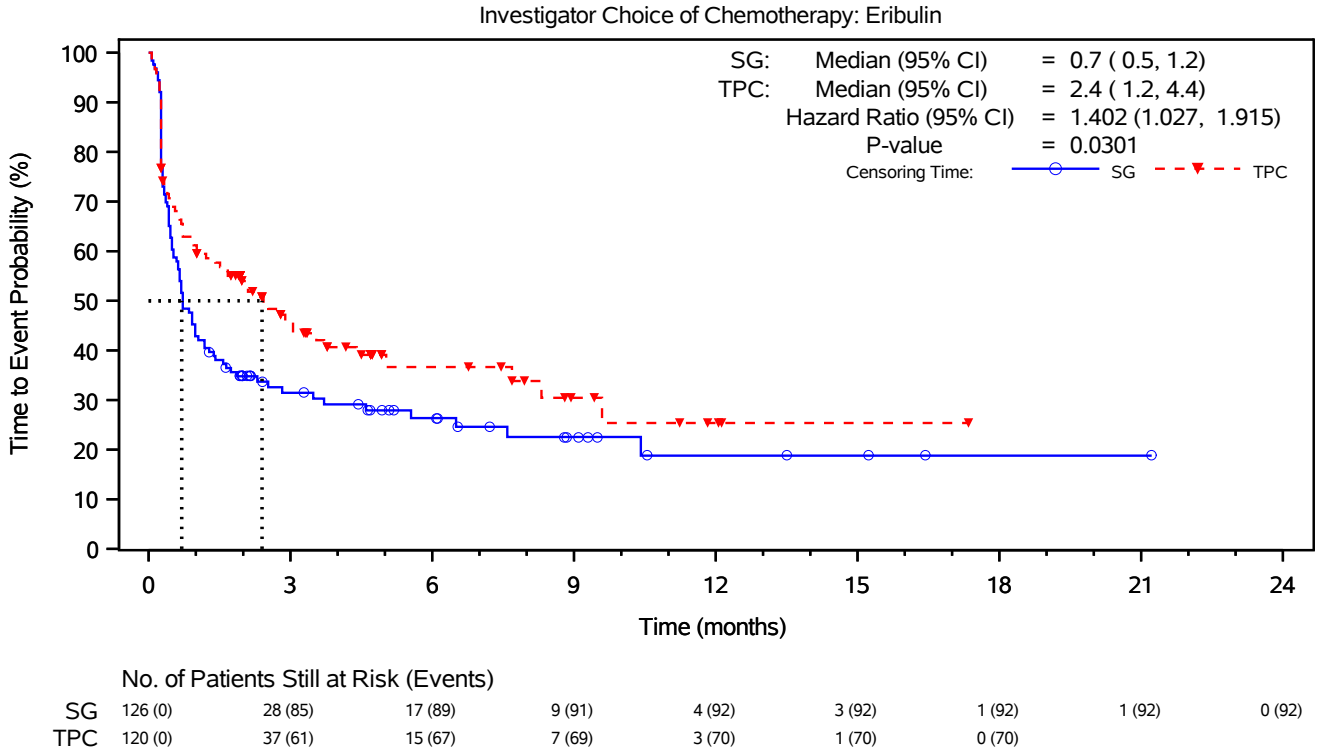
Figure 15.11.2.3.2: KM Plot for Time to the First Grade 3 or Higher TEAE by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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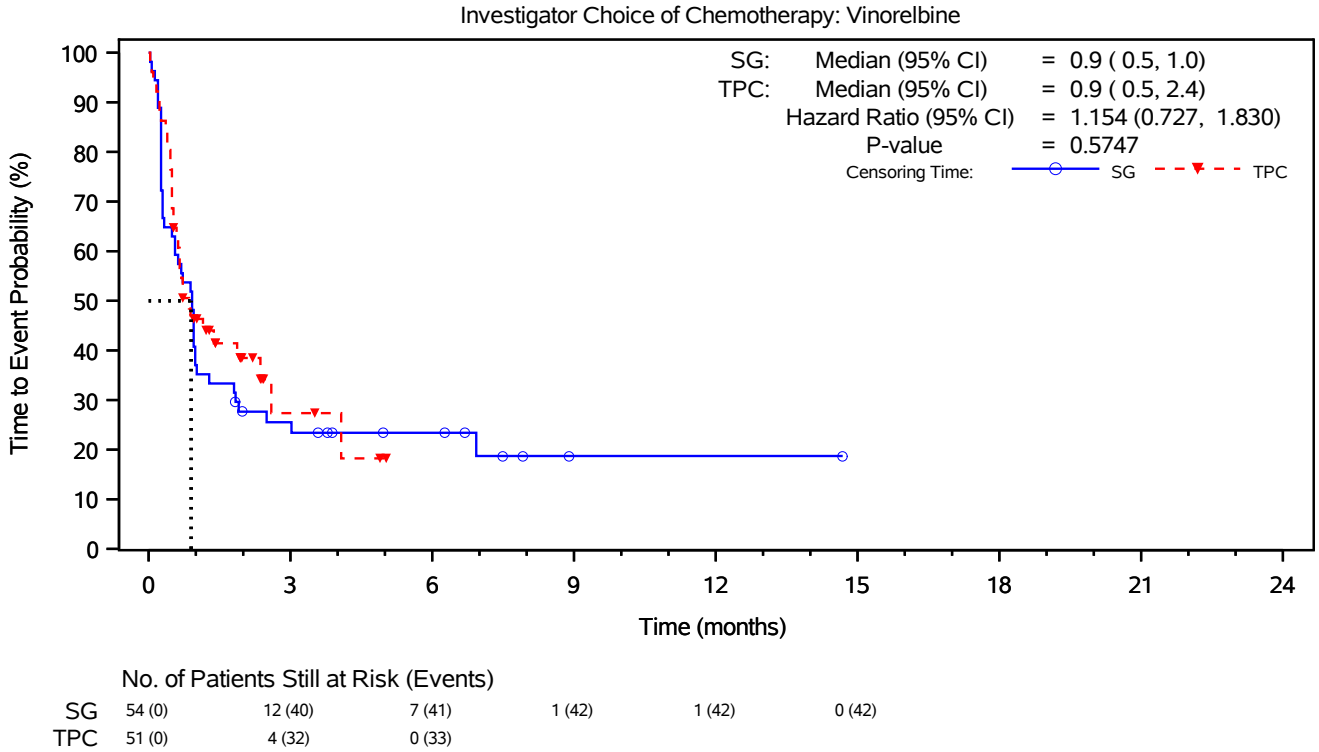
Figure 15.11.2.3.2: KM Plot for Time to the First Grade 3 or Higher TEAE by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9206
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	5 (5.3%)	2 (2.2%)	
Patients (%) Without Events (Censored)	90 (94.7%)	90 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.757 (0.334, 9.252)
p-value			0.5007
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	9 (8.5%)	4 (3.9%)	
Patients (%) Without Events (Censored)	97 (91.5%)	98 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.814 (0.554, 5.935)
p-value			0.3183

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9889
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	11 (5.7%)	6 (3.2%)	
Patients (%) Without Events (Censored)	181 (94.3%)	180 (96.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.450 (0.531, 3.960)
p-value			0.4663
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	3 (33.3%)	0	
Patients (%) Without Events (Censored)	6 (66.7%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (0.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1247

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9907
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	12 (6.7%)	6 (3.5%)	
Patients (%) Without Events (Censored)	168 (93.3%)	165 (96.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.535 (0.571, 4.125)
p-value			0.3921
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	0	
Patients (%) Without Events (Censored)	19 (90.5%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2314

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.1416
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	5 (3.2%)	4 (2.7%)	
Patients (%) Without Events (Censored)	150 (96.8%)	143 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.106 (0.297, 4.128)
p-value			0.8800
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	9 (19.6%)	2 (4.3%)	
Patients (%) Without Events (Censored)	37 (80.4%)	45 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.963 (0.853, 18.413)
p-value			0.0579

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.8537
Race: White			
Total Patients	141	132	
Patients (%) With Events	11 (7.8%)	5 (3.8%)	
Patients (%) Without Events (Censored)	130 (92.2%)	127 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.491 (0.511, 4.349)
p-value			0.4620
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	1 (6.3%)	
Patients (%) Without Events (Censored)	12 (92.3%)	15 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.192 (0.075, 19.059)
p-value			0.9012

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.5589
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	1 (1.1%)	1 (1.1%)	
Patients (%) Without Events (Censored)	86 (98.9%)	89 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.714 (0.045, 11.415)
p-value			0.8106
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	13 (11.4%)	5 (4.8%)	
Patients (%) Without Events (Censored)	101 (88.6%)	99 (95.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.976 (0.699, 5.583)
p-value			0.1908

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9820
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	9 (7.3%)	4 (3.3%)	
Patients (%) Without Events (Censored)	114 (92.7%)	117 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.882 (0.577, 6.137)
p-value			0.2870
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	5 (6.4%)	2 (2.7%)	
Patients (%) Without Events (Censored)	73 (93.6%)	71 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.691 (0.319, 8.957)
p-value			0.5321

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.5759
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	9 (7.8%)	3 (2.5%)	
Patients (%) Without Events (Censored)	107 (92.2%)	116 (97.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.268 (0.602, 8.541)
p-value			0.2145
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	5 (6.3%)	3 (4.1%)	
Patients (%) Without Events (Censored)	75 (93.8%)	70 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.360 (0.325, 5.699)
p-value			0.6724

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9889
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	0	
Patients (%) Without Events (Censored)	18 (85.7%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (4.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0681
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	8 (6.3%)	3 (2.5%)	
Patients (%) Without Events (Censored)	118 (93.7%)	117 (97.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.339 (0.620, 8.827)
p-value			0.1968
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	
Patients (%) With Events	3 (5.6%)	3 (5.9%)	
Patients (%) Without Events (Censored)	51 (94.4%)	48 (94.1%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (13.0, NE)	NE (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.433 (0.066, 2.842)
p-value			0.3725

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9903
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	13 (7.2%)	6 (3.4%)	
Patients (%) Without Events (Censored)	168 (92.8%)	170 (96.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.772 (0.669, 4.696)
p-value			0.2435

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9890
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	11 (6.2%)	6 (3.5%)	
Patients (%) Without Events (Censored)	166 (93.8%)	165 (96.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.462 (0.536, 3.986)
p-value			0.4553
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	3 (12.5%)	0	
Patients (%) Without Events (Censored)	21 (87.5%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1266

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.4044
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	6 (4.9%)	4 (3.1%)	
Patients (%) Without Events (Censored)	116 (95.1%)	125 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.179 (0.325, 4.286)
p-value			0.8019
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	8 (10.1%)	2 (3.1%)	
Patients (%) Without Events (Censored)	71 (89.9%)	63 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.923 (0.619, 13.793)
p-value			0.1555

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Interaction p-value			0.9925
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	2 (2.9%)	3 (4.2%)	
Patients (%) Without Events (Censored)	66 (97.1%)	69 (95.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.662 (0.110, 3.968)
p-value			0.6494
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	8 (11.3%)	2 (2.7%)	
Patients (%) Without Events (Censored)	63 (88.7%)	72 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.051 (0.636, 14.634)
p-value			0.1440
Trop2: H-Score > 200			
Total Patients	40	26	
Patients (%) With Events	2 (5.0%)	0	
Patients (%) Without Events (Censored)	38 (95.0%)	26 (100.0%)	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.5.2: Time to the First TEAE Leading to Any Study Drug Discontinuation by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3124

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9150
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	90 (94.7%)	74 (80.4%)	
Patients (%) Without Events (Censored)	5 (5.3%)	18 (19.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.5 (0.4, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.506 (1.105, 2.052)
p-value			0.0096
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	97 (91.5%)	83 (81.4%)	
Patients (%) Without Events (Censored)	9 (8.5%)	19 (18.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.4 (0.3, 0.5)	0.7 (0.5, 1.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.617 (1.201, 2.176)
p-value			0.0014

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.8643
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	60 (63.2%)	25 (27.2%)	
Patients (%) Without Events (Censored)	35 (36.8%)	67 (72.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (0.9, 3.4)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.915 (1.827, 4.652)
p-value			<0.0001
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	60 (56.6%)	24 (23.5%)	
Patients (%) Without Events (Censored)	46 (43.4%)	78 (76.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (1.0, 6.0)	NE (5.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.182 (1.977, 5.123)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.1207
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	7 (7.4%)	3 (3.3%)	
Patients (%) Without Events (Censored)	88 (92.6%)	89 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.260 (0.584, 8.741)
p-value			0.2251
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	5 (4.7%)	8 (7.8%)	
Patients (%) Without Events (Censored)	101 (95.3%)	94 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.558 (0.182, 1.707)
p-value			0.2998

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.7002
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	29 (30.5%)	17 (18.5%)	
Patients (%) Without Events (Censored)	66 (69.5%)	75 (81.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.3, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.585 (0.870, 2.889)
p-value			0.1270
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	27 (25.5%)	18 (17.6%)	
Patients (%) Without Events (Censored)	79 (74.5%)	84 (82.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (28.1, NE)	NE (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.373 (0.752, 2.508)
p-value			0.3026

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.2623
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	43 (45.3%)	26 (28.3%)	
Patients (%) Without Events (Censored)	52 (54.7%)	66 (71.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.9 (4.3, 13.7)	NE (5.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.388 (0.852, 2.261)
p-value			0.1864
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	33 (31.1%)	29 (28.4%)	
Patients (%) Without Events (Censored)	73 (68.9%)	73 (71.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	15.1 (13.4, 21.1)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.951 (0.573, 1.578)
p-value			0.8419

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.3628
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	18 (18.9%)	23 (25.0%)	
Patients (%) Without Events (Censored)	77 (81.1%)	69 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.8, NE)	NE (9.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.596 (0.320, 1.110)
p-value			0.0999
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	17 (16.0%)	31 (30.4%)	
Patients (%) Without Events (Censored)	89 (84.0%)	71 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	6.2 (5.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.371 (0.203, 0.679)
p-value			0.0008

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.0523
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	74 (77.9%)	44 (47.8%)	
Patients (%) Without Events (Censored)	21 (22.1%)	48 (52.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	4.4 (2.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.096 (1.439, 3.052)
p-value			<0.0001
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	73 (68.9%)	59 (57.8%)	
Patients (%) Without Events (Censored)	33 (31.1%)	43 (42.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 1.3)	1.9 (0.7, 4.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.298 (0.919, 1.831)
p-value			0.1432

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9630
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	178 (92.7%)	150 (80.6%)	
Patients (%) Without Events (Censored)	14 (7.3%)	36 (19.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.6 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.545 (1.241, 1.924)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	9 (100.0%)	7 (87.5%)	
Patients (%) Without Events (Censored)	0	1 (12.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.8)	0.6 (0.2, 1.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.023 (0.667, 6.137)
p-value			0.1859

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.8063
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	115 (59.9%)	47 (25.3%)	
Patients (%) Without Events (Censored)	77 (40.1%)	139 (74.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.3, 3.3)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.077 (2.190, 4.324)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	5 (55.6%)	2 (25.0%)	
Patients (%) Without Events (Censored)	4 (44.4%)	6 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.8 (0.2, NE)	NE (0.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.359 (0.444, 12.540)
p-value			0.3007

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			1.0000
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	12 (6.3%)	11 (5.9%)	
Patients (%) Without Events (Censored)	180 (93.8%)	175 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.019 (0.450, 2.311)
p-value			0.9641
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.9786
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	54 (28.1%)	35 (18.8%)	
Patients (%) Without Events (Censored)	138 (71.9%)	151 (81.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (28.1, NE)	NE (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.418 (0.924, 2.177)
p-value			0.1097
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	2 (22.2%)	0	
Patients (%) Without Events (Censored)	7 (77.8%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2416

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.1780
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	71 (37.0%)	54 (29.0%)	
Patients (%) Without Events (Censored)	121 (63.0%)	132 (71.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (6.5, 15.8)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.108 (0.776, 1.580)
p-value			0.5740
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	5 (55.6%)	1 (12.5%)	
Patients (%) Without Events (Censored)	4 (44.4%)	7 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.2 (0.7, NE)	NE (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.059 (0.473, 34.871)
p-value			0.1668

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.3072
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	33 (17.2%)	53 (28.5%)	
Patients (%) Without Events (Censored)	159 (82.8%)	133 (71.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (6.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.451 (0.290, 0.703)
p-value			0.0003
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	2 (22.2%)	1 (12.5%)	
Patients (%) Without Events (Censored)	7 (77.8%)	7 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.1, NE)	NE (5.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.097 (0.098, 12.287)
p-value			0.9400

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.5947
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	141 (73.4%)	98 (52.7%)	
Patients (%) Without Events (Censored)	51 (26.6%)	88 (47.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.9)	2.5 (1.6, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.653 (1.275, 2.141)
p-value			0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	6 (66.7%)	5 (62.5%)	
Patients (%) Without Events (Censored)	3 (33.3%)	3 (37.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, NE)	1.3 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.288 (0.392, 4.229)
p-value			0.6818

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.4786
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	167 (92.8%)	137 (80.1%)	
Patients (%) Without Events (Censored)	13 (7.2%)	34 (19.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.7 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.593 (1.268, 2.001)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	20 (95.2%)	20 (87.0%)	
Patients (%) Without Events (Censored)	1 (4.8%)	3 (13.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, 0.7)	0.4 (0.3, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.246 (0.667, 2.328)
p-value			0.4737

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9429
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	108 (60.0%)	44 (25.7%)	
Patients (%) Without Events (Censored)	72 (40.0%)	127 (74.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.2, 3.4)	NE (8.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.053 (2.148, 4.338)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	12 (57.1%)	5 (21.7%)	
Patients (%) Without Events (Censored)	9 (42.9%)	18 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.7 (0.5, NE)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.150 (1.100, 9.024)
p-value			0.0245

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.3158
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	11 (6.1%)	8 (4.7%)	
Patients (%) Without Events (Censored)	169 (93.9%)	163 (95.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.261 (0.507, 3.135)
p-value			0.6173
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	3 (13.0%)	
Patients (%) Without Events (Censored)	20 (95.2%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.349 (0.036, 3.358)
p-value			0.3399

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.6112
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	49 (27.2%)	30 (17.5%)	
Patients (%) Without Events (Censored)	131 (72.8%)	141 (82.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (28.1, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.447 (0.916, 2.286)
p-value			0.1116
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	7 (33.3%)	5 (21.7%)	
Patients (%) Without Events (Censored)	14 (66.7%)	18 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.3 (1.0, NE)	11.7 (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.543 (0.736, 8.781)
p-value			0.1293

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.1877
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	69 (38.3%)	45 (26.3%)	
Patients (%) Without Events (Censored)	111 (61.7%)	126 (73.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.4 (6.4, 15.8)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.289 (0.885, 1.880)
p-value			0.1847
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	7 (33.3%)	10 (43.5%)	
Patients (%) Without Events (Censored)	14 (66.7%)	13 (56.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.1 (1.4, NE)	NE (0.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.735 (0.279, 1.938)
p-value			0.5374

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.5349
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	34 (18.9%)	50 (29.2%)	
Patients (%) Without Events (Censored)	146 (81.1%)	121 (70.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	9.7 (6.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.481 (0.309, 0.748)
p-value			0.0009
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	4 (17.4%)	
Patients (%) Without Events (Censored)	20 (95.2%)	19 (82.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (6.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.233 (0.025, 2.176)
p-value			0.1680

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.1534
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	135 (75.0%)	89 (52.0%)	
Patients (%) Without Events (Censored)	45 (25.0%)	82 (48.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.9)	4.1 (1.6, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.726 (1.319, 2.259)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	12 (57.1%)	14 (60.9%)	
Patients (%) Without Events (Censored)	9 (42.9%)	9 (39.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.6, NE)	1.9 (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.020 (0.467, 2.228)
p-value			0.9767

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.0131
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	143 (92.3%)	119 (81.0%)	
Patients (%) Without Events (Censored)	12 (7.7%)	28 (19.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.4 (0.3, 0.5)	0.5 (0.4, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.346 (1.054, 1.720)
p-value			0.0168
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	44 (95.7%)	38 (80.9%)	
Patients (%) Without Events (Censored)	2 (4.3%)	9 (19.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.4)	0.7 (0.5, 1.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.676 (1.701, 4.210)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.2896
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	87 (56.1%)	35 (23.8%)	
Patients (%) Without Events (Censored)	68 (43.9%)	112 (76.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (1.5, 6.0)	NE (8.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.806 (1.893, 4.161)
p-value			<0.0001
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	33 (71.7%)	14 (29.8%)	
Patients (%) Without Events (Censored)	13 (28.3%)	33 (70.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 2.7)	7.6 (4.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.187 (2.228, 7.868)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.0750
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	7 (4.5%)	10 (6.8%)	
Patients (%) Without Events (Censored)	148 (95.5%)	137 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.622 (0.236, 1.634)
p-value			0.3295
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	5 (10.9%)	1 (2.1%)	
Patients (%) Without Events (Censored)	41 (89.1%)	46 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.438 (0.635, 46.551)
p-value			0.0824

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.6872
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	43 (27.7%)	24 (16.3%)	
Patients (%) Without Events (Censored)	112 (72.3%)	123 (83.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.601 (0.970, 2.643)
p-value			0.0630
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	13 (28.3%)	11 (23.4%)	
Patients (%) Without Events (Censored)	33 (71.7%)	36 (76.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (5.6, NE)	11.7 (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.340 (0.589, 3.048)
p-value			0.4856

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.1307
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	55 (35.5%)	43 (29.3%)	
Patients (%) Without Events (Censored)	100 (64.5%)	104 (70.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.7 (7.9, 15.8)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.020 (0.683, 1.524)
p-value			0.9226
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	21 (45.7%)	12 (25.5%)	
Patients (%) Without Events (Censored)	25 (54.3%)	35 (74.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.8 (2.7, NE)	NE (3.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.964 (0.965, 3.997)
p-value			0.0582

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.1611
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	25 (16.1%)	43 (29.3%)	
Patients (%) Without Events (Censored)	130 (83.9%)	104 (70.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	9.1 (5.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.390 (0.236, 0.645)
p-value			0.0001
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	10 (21.7%)	11 (23.4%)	
Patients (%) Without Events (Censored)	36 (78.3%)	36 (76.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	14.8 (14.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.801 (0.338, 1.896)
p-value			0.6106

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.5348
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	115 (74.2%)	80 (54.4%)	
Patients (%) Without Events (Censored)	40 (25.8%)	67 (45.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.4 (0.8, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.534 (1.152, 2.044)
p-value			0.0032
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	32 (69.6%)	23 (48.9%)	
Patients (%) Without Events (Censored)	14 (30.4%)	24 (51.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.7, 1.0)	4.4 (1.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.919 (1.117, 3.296)
p-value			0.0169

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.2200
Race: White			
Total Patients	141	132	
Patients (%) With Events	132 (93.6%)	107 (81.1%)	
Patients (%) Without Events (Censored)	9 (6.4%)	25 (18.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.7 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.633 (1.263, 2.113)
p-value			0.0002
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	13 (100.0%)	13 (81.3%)	
Patients (%) Without Events (Censored)	0	3 (18.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.0, 0.3)	0.5 (0.3, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.599 (1.166, 5.796)
p-value			0.0194

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.4806
Race: White			
Total Patients	141	132	
Patients (%) With Events	85 (60.3%)	33 (25.0%)	
Patients (%) Without Events (Censored)	56 (39.7%)	99 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.2, 2.9)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.088 (2.062, 4.625)
p-value			<0.0001
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	7 (53.8%)	5 (31.3%)	
Patients (%) Without Events (Censored)	6 (46.2%)	11 (68.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.0 (0.1, NE)	NE (1.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.717 (0.522, 5.644)
p-value			0.3648

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9999
Race: White			
Total Patients	141	132	
Patients (%) With Events	8 (5.7%)	10 (7.6%)	
Patients (%) Without Events (Censored)	133 (94.3%)	122 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.702 (0.277, 1.779)
p-value			0.4546
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.1706
Race: White			
Total Patients	141	132	
Patients (%) With Events	41 (29.1%)	25 (18.9%)	
Patients (%) Without Events (Censored)	100 (70.9%)	107 (81.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (12.0, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.427 (0.864, 2.357)
p-value			0.1637
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	6 (46.2%)	2 (12.5%)	
Patients (%) Without Events (Censored)	7 (53.8%)	14 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (0.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.579 (0.921, 22.754)
p-value			0.0432

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.3029
Race: White			
Total Patients	141	132	
Patients (%) With Events	54 (38.3%)	41 (31.1%)	
Patients (%) Without Events (Censored)	87 (61.7%)	91 (68.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.7 (7.9, 15.9)	NE (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.039 (0.689, 1.568)
p-value			0.8550
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	4 (30.8%)	2 (12.5%)	
Patients (%) Without Events (Censored)	9 (69.2%)	14 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.4 (2.9, NE)	NE (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.653 (0.479, 14.686)
p-value			0.2459

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.3837
Race: White			
Total Patients	141	132	
Patients (%) With Events	33 (23.4%)	39 (29.5%)	
Patients (%) Without Events (Censored)	108 (76.6%)	93 (70.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.8, NE)	NE (5.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.610 (0.381, 0.976)
p-value			0.0374
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	4 (25.0%)	
Patients (%) Without Events (Censored)	12 (92.3%)	12 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.9, NE)	9.1 (9.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.307 (0.034, 2.772)
p-value			0.2661

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9751
Race: White			
Total Patients	141	132	
Patients (%) With Events	103 (73.0%)	72 (54.5%)	
Patients (%) Without Events (Censored)	38 (27.0%)	60 (45.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.4 (0.8, 4.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.561 (1.154, 2.112)
p-value			0.0036
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	11 (84.6%)	10 (62.5%)	
Patients (%) Without Events (Censored)	2 (15.4%)	6 (37.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 3.1)	0.8 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.581 (0.670, 3.734)
p-value			0.3131

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.3496
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	81 (93.1%)	71 (78.9%)	
Patients (%) Without Events (Censored)	6 (6.9%)	19 (21.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.5)	0.7 (0.5, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.707 (1.235, 2.358)
p-value			0.0010
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	106 (93.0%)	86 (82.7%)	
Patients (%) Without Events (Censored)	8 (7.0%)	18 (17.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.5)	0.5 (0.4, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.411 (1.060, 1.878)
p-value			0.0202

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.2466
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	53 (60.9%)	20 (22.2%)	
Patients (%) Without Events (Censored)	34 (39.1%)	70 (77.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.9, 4.3)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.831 (2.286, 6.420)
p-value			<0.0001
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	67 (58.8%)	29 (27.9%)	
Patients (%) Without Events (Censored)	47 (41.2%)	75 (72.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.7 (1.0, 5.1)	8.5 (5.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.528 (1.633, 3.915)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.4242
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	7 (8.0%)	5 (5.6%)	
Patients (%) Without Events (Censored)	80 (92.0%)	85 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.427 (0.453, 4.497)
p-value			0.5440
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	5 (4.4%)	6 (5.8%)	
Patients (%) Without Events (Censored)	109 (95.6%)	98 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.715 (0.218, 2.344)
p-value			0.5787

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.3620
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	28 (32.2%)	15 (16.7%)	
Patients (%) Without Events (Censored)	59 (67.8%)	75 (83.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (7.3, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.818 (0.964, 3.429)
p-value			0.0610
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	28 (24.6%)	20 (19.2%)	
Patients (%) Without Events (Censored)	86 (75.4%)	84 (80.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.236 (0.696, 2.196)
p-value			0.4722

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.4743
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	34 (39.1%)	22 (24.4%)	
Patients (%) Without Events (Censored)	53 (60.9%)	68 (75.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (4.6, 21.1)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.365 (0.796, 2.342)
p-value			0.2577
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	42 (36.8%)	33 (31.7%)	
Patients (%) Without Events (Censored)	72 (63.2%)	71 (68.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	15.1 (5.2, 15.9)	6.6 (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.051 (0.665, 1.659)
p-value			0.8282

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.5599
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	16 (18.4%)	24 (26.7%)	
Patients (%) Without Events (Censored)	71 (81.6%)	66 (73.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (6.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.562 (0.297, 1.063)
p-value			0.0723
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	19 (16.7%)	30 (28.8%)	
Patients (%) Without Events (Censored)	95 (83.3%)	74 (71.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.8, NE)	9.7 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.397 (0.220, 0.718)
p-value			0.0016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.8534
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	69 (79.3%)	49 (54.4%)	
Patients (%) Without Events (Censored)	18 (20.7%)	41 (45.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 1.0)	2.4 (0.7, 8.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.662 (1.149, 2.404)
p-value			0.0058
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	78 (68.4%)	54 (51.9%)	
Patients (%) Without Events (Censored)	36 (31.6%)	50 (48.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.5 (1.2, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.604 (1.133, 2.272)
p-value			0.0080

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.0023
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	111 (90.2%)	98 (81.0%)	
Patients (%) Without Events (Censored)	12 (9.8%)	23 (19.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.4, 0.7)	0.6 (0.4, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.255 (0.954, 1.650)
p-value			0.0993
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	76 (97.4%)	59 (80.8%)	
Patients (%) Without Events (Censored)	2 (2.6%)	14 (19.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (NE, NE)	0.7 (0.5, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.396 (1.689, 3.399)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.1153
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	77 (62.6%)	27 (22.3%)	
Patients (%) Without Events (Censored)	46 (37.4%)	94 (77.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.0, 2.9)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.832 (2.467, 5.952)
p-value			<0.0001
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	43 (55.1%)	22 (30.1%)	
Patients (%) Without Events (Censored)	35 (44.9%)	51 (69.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.7 (1.0, 8.2)	NE (3.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.179 (1.302, 3.646)
p-value			0.0024

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.1039
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	9 (7.3%)	5 (4.1%)	
Patients (%) Without Events (Censored)	114 (92.7%)	116 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.788 (0.599, 5.337)
p-value			0.2916
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	3 (3.8%)	6 (8.2%)	
Patients (%) Without Events (Censored)	75 (96.2%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.414 (0.103, 1.659)
p-value			0.1995

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.2962
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	28 (22.8%)	21 (17.4%)	
Patients (%) Without Events (Censored)	95 (77.2%)	100 (82.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.0, NE)	NE (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.193 (0.675, 2.109)
p-value			0.5421
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	28 (35.9%)	14 (19.2%)	
Patients (%) Without Events (Censored)	50 (64.1%)	59 (80.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (7.2, NE)	NE (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.944 (1.019, 3.708)
p-value			0.0414

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.8584
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	47 (38.2%)	34 (28.1%)	
Patients (%) Without Events (Censored)	76 (61.8%)	87 (71.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (5.2, 15.8)	NE (6.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.208 (0.776, 1.881)
p-value			0.4029
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	29 (37.2%)	21 (28.8%)	
Patients (%) Without Events (Censored)	49 (62.8%)	52 (71.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.7 (4.1, NE)	6.5 (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.103 (0.624, 1.947)
p-value			0.7346

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.7890
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	17 (13.8%)	28 (23.1%)	
Patients (%) Without Events (Censored)	106 (86.2%)	93 (76.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.500 (0.273, 0.918)
p-value			0.0223
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	18 (23.1%)	26 (35.6%)	
Patients (%) Without Events (Censored)	60 (76.9%)	47 (64.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (10.2, NE)	6.1 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.422 (0.230, 0.777)
p-value			0.0044

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.0413
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	83 (67.5%)	67 (55.4%)	
Patients (%) Without Events (Censored)	40 (32.5%)	54 (44.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 1.3)	2.7 (1.0, 6.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.320 (0.955, 1.825)
p-value			0.0879
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	64 (82.1%)	36 (49.3%)	
Patients (%) Without Events (Censored)	14 (17.9%)	37 (50.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, 0.7)	2.4 (0.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.249 (1.493, 3.390)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.2724
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	107 (92.2%)	96 (80.7%)	
Patients (%) Without Events (Censored)	9 (7.8%)	23 (19.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, 0.5)	0.7 (0.4, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.470 (1.112, 1.944)
p-value			0.0056
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	76 (95.0%)	60 (82.2%)	
Patients (%) Without Events (Censored)	4 (5.0%)	13 (17.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.3)	0.5 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.835 (1.304, 2.583)
p-value			0.0006

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.3947
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	71 (61.2%)	32 (26.9%)	
Patients (%) Without Events (Censored)	45 (38.8%)	87 (73.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (1.3, 3.4)	NE (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.759 (1.814, 4.199)
p-value			<0.0001
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	48 (60.0%)	17 (23.3%)	
Patients (%) Without Events (Censored)	32 (40.0%)	56 (76.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.5 (0.7, 5.1)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.634 (2.086, 6.329)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.4058
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	7 (6.0%)	5 (4.2%)	
Patients (%) Without Events (Censored)	109 (94.0%)	114 (95.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.427 (0.453, 4.499)
p-value			0.5439
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	5 (6.3%)	6 (8.2%)	
Patients (%) Without Events (Censored)	75 (93.8%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.708 (0.216, 2.321)
p-value			0.5679

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.5432
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	32 (27.6%)	22 (18.5%)	
Patients (%) Without Events (Censored)	84 (72.4%)	97 (81.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.0, NE)	NE (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.347 (0.778, 2.334)
p-value			0.2862
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	23 (28.8%)	12 (16.4%)	
Patients (%) Without Events (Censored)	57 (71.3%)	61 (83.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (NE, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.741 (0.861, 3.517)
p-value			0.1186

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.6616
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	46 (39.7%)	32 (26.9%)	
Patients (%) Without Events (Censored)	70 (60.3%)	87 (73.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (5.2, 15.1)	NE (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.249 (0.793, 1.967)
p-value			0.3376
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	29 (36.3%)	23 (31.5%)	
Patients (%) Without Events (Censored)	51 (63.8%)	50 (68.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	15.8 (4.6, 21.1)	6.6 (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.067 (0.617, 1.846)
p-value			0.8132

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.7888
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	19 (16.4%)	29 (24.4%)	
Patients (%) Without Events (Censored)	97 (83.6%)	90 (75.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.8, NE)	NE (6.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.452 (0.249, 0.823)
p-value			0.0077
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	14 (17.5%)	25 (34.2%)	
Patients (%) Without Events (Censored)	66 (82.5%)	48 (65.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	9.7 (5.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.433 (0.225, 0.833)
p-value			0.0099

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.1196
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	80 (69.0%)	65 (54.6%)	
Patients (%) Without Events (Censored)	36 (31.0%)	54 (45.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.1)	2.4 (1.0, 4.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.400 (1.007, 1.947)
p-value			0.0414
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	65 (81.3%)	38 (52.1%)	
Patients (%) Without Events (Censored)	15 (18.8%)	35 (47.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.4, 0.8)	2.7 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.068 (1.383, 3.093)
p-value			0.0004

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.1786
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	19 (90.5%)	19 (82.6%)	
Patients (%) Without Events (Censored)	2 (9.5%)	4 (17.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.5)	0.7 (0.5, 1.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.029 (1.052, 3.913)
p-value			0.0315
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	119 (94.4%)	97 (80.8%)	
Patients (%) Without Events (Censored)	7 (5.6%)	23 (19.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.6 (0.4, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.570 (1.195, 2.063)
p-value			0.0010
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	49 (90.7%)	41 (80.4%)	
Patients (%) Without Events (Censored)	5 (9.3%)	10 (19.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.7)	0.5 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.250 (0.823, 1.899)
p-value			0.2997

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.7939
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	13 (61.9%)	11 (47.8%)	
Patients (%) Without Events (Censored)	8 (38.1%)	12 (52.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, NE)	6.7 (2.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.746 (0.777, 3.923)
p-value			0.1718
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	75 (59.5%)	24 (20.0%)	
Patients (%) Without Events (Censored)	51 (40.5%)	96 (80.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.0, 3.6)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.240 (2.673, 6.728)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	32 (59.3%)	14 (27.5%)	
Patients (%) Without Events (Censored)	22 (40.7%)	37 (72.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (1.2, 8.2)	4.9 (2.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.998 (1.053, 3.791)
p-value			0.0311

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9881
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	0	
Patients (%) Without Events (Censored)	20 (95.2%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2953
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	8 (6.3%)	7 (5.8%)	
Patients (%) Without Events (Censored)	118 (93.7%)	113 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.083 (0.393, 2.986)
p-value			0.8773
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (5.6%)	4 (7.8%)	
Patients (%) Without Events (Censored)	51 (94.4%)	47 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.536 (0.118, 2.434)
p-value			0.4124

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.0333
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	4 (19.0%)	10 (43.5%)	
Patients (%) Without Events (Censored)	17 (81.0%)	13 (56.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	11.2 (1.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.468 (0.145, 1.505)
p-value			0.1896
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	36 (28.6%)	19 (15.8%)	
Patients (%) Without Events (Censored)	90 (71.4%)	101 (84.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (12.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.813 (1.036, 3.173)
p-value			0.0340
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	16 (29.6%)	6 (11.8%)	
Patients (%) Without Events (Censored)	38 (70.4%)	45 (88.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.947 (0.746, 5.084)
p-value			0.1679

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9287
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	8 (38.1%)	7 (30.4%)	
Patients (%) Without Events (Censored)	13 (61.9%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	15.8 (3.9, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.095 (0.383, 3.126)
p-value			0.8655
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	48 (38.1%)	36 (30.0%)	
Patients (%) Without Events (Censored)	78 (61.9%)	84 (70.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.4 (5.6, 15.9)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.173 (0.761, 1.808)
p-value			0.4718
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	20 (37.0%)	12 (23.5%)	
Patients (%) Without Events (Censored)	34 (63.0%)	39 (76.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.1 (3.8, NE)	5.5 (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.063 (0.502, 2.248)
p-value			0.8718

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.5714
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	7 (30.4%)	
Patients (%) Without Events (Censored)	18 (85.7%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.480 (0.124, 1.859)
p-value			0.2794
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	23 (18.3%)	41 (34.2%)	
Patients (%) Without Events (Censored)	103 (81.7%)	79 (65.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.8, NE)	9.1 (5.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.408 (0.243, 0.685)
p-value			0.0005
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	9 (16.7%)	6 (11.8%)	
Patients (%) Without Events (Censored)	45 (83.3%)	45 (88.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.858 (0.295, 2.491)
p-value			0.7776

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.0014
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	16 (76.2%)	5 (21.7%)	
Patients (%) Without Events (Censored)	5 (23.8%)	18 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.4, 1.0)	NE (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.844 (2.460, 19.045)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	91 (72.2%)	65 (54.2%)	
Patients (%) Without Events (Censored)	35 (27.8%)	55 (45.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.9)	2.5 (1.6, 6.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.548 (1.123, 2.133)
p-value			0.0059
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	40 (74.1%)	33 (64.7%)	
Patients (%) Without Events (Censored)	14 (25.9%)	18 (35.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.6, 1.6)	0.7 (0.5, 1.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.008 (0.632, 1.607)
p-value			0.9738

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.4438
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	12 (92.3%)	11 (78.6%)	
Patients (%) Without Events (Censored)	1 (7.7%)	3 (21.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.4 (0.2, 0.7)	0.5 (0.3, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.188 (0.513, 2.750)
p-value			0.7238
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	168 (92.8%)	142 (80.7%)	
Patients (%) Without Events (Censored)	13 (7.2%)	34 (19.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.6 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.574 (1.256, 1.972)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.4440
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	7 (53.8%)	1 (7.1%)	
Patients (%) Without Events (Censored)	6 (46.2%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	8.2 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.456 (0.777, 53.663)
p-value			0.0475
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	108 (59.7%)	47 (26.7%)	
Patients (%) Without Events (Censored)	73 (40.3%)	129 (73.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.2, 2.9)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.954 (2.096, 4.164)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9909
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2770
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	10 (5.5%)	10 (5.7%)	
Patients (%) Without Events (Censored)	171 (94.5%)	166 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.945 (0.393, 2.271)
p-value			0.8984

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.7441
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	5 (38.5%)	2 (14.3%)	
Patients (%) Without Events (Censored)	8 (61.5%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.985 (0.359, 10.969)
p-value			0.4232
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	49 (27.1%)	31 (17.6%)	
Patients (%) Without Events (Censored)	132 (72.9%)	145 (82.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (28.1, NE)	NE (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.494 (0.950, 2.350)
p-value			0.0809

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.0502
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	3 (23.1%)	5 (35.7%)	
Patients (%) Without Events (Censored)	10 (76.9%)	9 (64.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.9, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.112 (0.012, 1.036)
p-value			0.0246
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	67 (37.0%)	48 (27.3%)	
Patients (%) Without Events (Censored)	114 (63.0%)	128 (72.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.4 (6.5, 15.9)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.257 (0.867, 1.823)
p-value			0.2263

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.2586
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	2 (15.4%)	5 (35.7%)	
Patients (%) Without Events (Censored)	11 (84.6%)	9 (64.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.1, NE)	4.6 (0.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.119 (0.019, 0.725)
p-value			0.0121
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	31 (17.1%)	47 (26.7%)	
Patients (%) Without Events (Censored)	150 (82.9%)	129 (73.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.8, NE)	NE (9.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.495 (0.313, 0.784)
p-value			0.0023

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.3625
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	10 (76.9%)	5 (35.7%)	
Patients (%) Without Events (Censored)	3 (23.1%)	9 (64.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 3.1)	NE (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.390 (0.813, 7.025)
p-value			0.1076
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	131 (72.4%)	97 (55.1%)	
Patients (%) Without Events (Censored)	50 (27.6%)	79 (44.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.4 (1.0, 4.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.529 (1.175, 1.990)
p-value			0.0014

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.5535
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	164 (92.7%)	137 (80.1%)	
Patients (%) Without Events (Censored)	13 (7.3%)	34 (19.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.5 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.592 (1.266, 2.002)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	23 (95.8%)	20 (87.0%)	
Patients (%) Without Events (Censored)	1 (4.2%)	3 (13.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.4 (0.2, 0.8)	0.7 (0.5, 1.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.286 (0.699, 2.365)
p-value			0.4256

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9713
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	103 (58.2%)	42 (24.6%)	
Patients (%) Without Events (Censored)	74 (41.8%)	129 (75.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (1.3, 4.3)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.055 (2.133, 4.377)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	17 (70.8%)	7 (30.4%)	
Patients (%) Without Events (Censored)	7 (29.2%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.3, 2.8)	8.5 (4.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.963 (1.224, 7.174)
p-value			0.0115

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9886
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	11 (6.2%)	11 (6.4%)	
Patients (%) Without Events (Censored)	166 (93.8%)	160 (93.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.934 (0.405, 2.154)
p-value			0.8715
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	1 (4.2%)	0	
Patients (%) Without Events (Censored)	23 (95.8%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3276

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.4114
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	50 (28.2%)	33 (19.3%)	
Patients (%) Without Events (Censored)	127 (71.8%)	138 (80.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (12.0, NE)	NE (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.386 (0.890, 2.158)
p-value			0.1485
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	6 (25.0%)	2 (8.7%)	
Patients (%) Without Events (Censored)	18 (75.0%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.757 (0.554, 13.731)
p-value			0.2000

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.7887
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	63 (35.6%)	47 (27.5%)	
Patients (%) Without Events (Censored)	114 (64.4%)	124 (72.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (6.5, 15.8)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.147 (0.785, 1.675)
p-value			0.4809
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	13 (54.2%)	8 (34.8%)	
Patients (%) Without Events (Censored)	11 (45.8%)	15 (65.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.4 (2.1, NE)	5.5 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.286 (0.530, 3.119)
p-value			0.5769

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.7323
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	29 (16.4%)	47 (27.5%)	
Patients (%) Without Events (Censored)	148 (83.6%)	124 (72.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	9.7 (6.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.461 (0.289, 0.736)
p-value			0.0009
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	6 (25.0%)	7 (30.4%)	
Patients (%) Without Events (Censored)	18 (75.0%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.8, NE)	NE (5.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.544 (0.172, 1.724)
p-value			0.2880

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.2807
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	133 (75.1%)	91 (53.2%)	
Patients (%) Without Events (Censored)	44 (24.9%)	80 (46.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.8)	2.4 (1.2, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.731 (1.324, 2.265)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	14 (58.3%)	12 (52.2%)	
Patients (%) Without Events (Censored)	10 (41.7%)	11 (47.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.7 (0.6, NE)	4.5 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.106 (0.510, 2.398)
p-value			0.8294

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9324
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	112 (91.8%)	104 (80.6%)	
Patients (%) Without Events (Censored)	10 (8.2%)	25 (19.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.7 (0.5, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.580 (1.208, 2.068)
p-value			0.0009
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	75 (94.9%)	53 (81.5%)	
Patients (%) Without Events (Censored)	4 (5.1%)	12 (18.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.5)	0.5 (0.3, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.501 (1.048, 2.150)
p-value			0.0238

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9246
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	73 (59.8%)	32 (24.8%)	
Patients (%) Without Events (Censored)	49 (40.2%)	97 (75.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.2, 4.3)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.091 (2.038, 4.687)
p-value			<0.0001
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	47 (59.5%)	17 (26.2%)	
Patients (%) Without Events (Censored)	32 (40.5%)	48 (73.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (0.8, 5.1)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.962 (1.698, 5.167)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.6265
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	7 (5.7%)	8 (6.2%)	
Patients (%) Without Events (Censored)	115 (94.3%)	121 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.881 (0.319, 2.429)
p-value			0.8060
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	5 (6.3%)	3 (4.6%)	
Patients (%) Without Events (Censored)	74 (93.7%)	62 (95.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.363 (0.326, 5.705)
p-value			0.6708

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.8842
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	38 (31.1%)	25 (19.4%)	
Patients (%) Without Events (Censored)	84 (68.9%)	104 (80.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (7.3, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.528 (0.918, 2.542)
p-value			0.1035
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	18 (22.8%)	10 (15.4%)	
Patients (%) Without Events (Censored)	61 (77.2%)	55 (84.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	11.7 (11.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.452 (0.669, 3.151)
p-value			0.3402

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.4357
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	50 (41.0%)	40 (31.0%)	
Patients (%) Without Events (Censored)	72 (59.0%)	89 (69.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.1 (5.2, 21.1)	NE (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.098 (0.722, 1.671)
p-value			0.6637
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	26 (32.9%)	15 (23.1%)	
Patients (%) Without Events (Censored)	53 (67.1%)	50 (76.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.4 (4.3, NE)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.429 (0.756, 2.701)
p-value			0.2695

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.8344
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	18 (14.8%)	31 (24.0%)	
Patients (%) Without Events (Censored)	104 (85.2%)	98 (76.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.444 (0.246, 0.801)
p-value			0.0056
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	17 (21.5%)	23 (35.4%)	
Patients (%) Without Events (Censored)	62 (78.5%)	42 (64.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (10.2, NE)	6.2 (3.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.490 (0.260, 0.923)
p-value			0.0245

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.5898
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	85 (69.7%)	64 (49.6%)	
Patients (%) Without Events (Censored)	37 (30.3%)	65 (50.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	4.1 (1.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.695 (1.224, 2.347)
p-value			0.0014
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	62 (78.5%)	39 (60.0%)	
Patients (%) Without Events (Censored)	17 (21.5%)	26 (40.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 1.0)	2.0 (0.6, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.453 (0.971, 2.174)
p-value			0.0646

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9817
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	62 (91.2%)	59 (81.9%)	
Patients (%) Without Events (Censored)	6 (8.8%)	13 (18.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	0.6 (0.5, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.762 (1.226, 2.531)
p-value			0.0023
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	64 (90.1%)	57 (77.0%)	
Patients (%) Without Events (Censored)	7 (9.9%)	17 (23.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.4 (0.3, 0.7)	0.5 (0.3, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.271 (0.887, 1.820)
p-value			0.1840
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	39 (97.5%)	22 (84.6%)	
Patients (%) Without Events (Censored)	1 (2.5%)	4 (15.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.5)	0.7 (0.5, 1.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.885 (1.100, 3.227)
p-value			0.0177

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.4025
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	33 (48.5%)	17 (23.6%)	
Patients (%) Without Events (Censored)	35 (51.5%)	55 (76.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.0 (0.7, NE)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.565 (1.427, 4.610)
p-value			0.0011
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	45 (63.4%)	14 (18.9%)	
Patients (%) Without Events (Censored)	26 (36.6%)	60 (81.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.7, 3.6)	NE (5.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.236 (2.321, 7.730)
p-value			<0.0001
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	25 (62.5%)	11 (42.3%)	
Patients (%) Without Events (Censored)	15 (37.5%)	15 (57.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (1.0, 8.2)	6.7 (1.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.809 (0.883, 3.708)
p-value			0.1002

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Hypersensitivity+			
Interaction p-value			0.5748
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	16 (23.5%)	13 (18.1%)	
Patients (%) Without Events (Censored)	52 (76.5%)	59 (81.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (11.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.417 (0.681, 2.949)
p-value			0.3579
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	20 (28.2%)	12 (16.2%)	
Patients (%) Without Events (Censored)	51 (71.8%)	62 (83.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.3, NE)	NE (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.504 (0.732, 3.094)
p-value			0.2639
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	13 (32.5%)	7 (26.9%)	
Patients (%) Without Events (Censored)	27 (67.5%)	19 (73.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	28.1 (5.2, NE)	NE (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.947 (0.371, 2.414)
p-value			0.9139

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.5194
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	21 (30.9%)	21 (29.2%)	
Patients (%) Without Events (Censored)	47 (69.1%)	51 (70.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.6, NE)	NE (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.031 (0.563, 1.888)
p-value			0.9247
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	25 (35.2%)	18 (24.3%)	
Patients (%) Without Events (Censored)	46 (64.8%)	56 (75.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	13.4 (9.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.954 (0.504, 1.806)
p-value			0.8804
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	20 (50.0%)	9 (34.6%)	
Patients (%) Without Events (Censored)	20 (50.0%)	17 (65.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.2 (3.7, 15.8)	NE (3.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.477 (0.666, 3.277)
p-value			0.3339

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.1109
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	10 (14.7%)	25 (34.7%)	
Patients (%) Without Events (Censored)	58 (85.3%)	47 (65.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	14.8 (14.8, NE)	9.1 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.310 (0.144, 0.667)
p-value			0.0016
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	10 (14.1%)	16 (21.6%)	
Patients (%) Without Events (Censored)	61 (85.9%)	58 (78.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (5.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.401 (0.178, 0.903)
p-value			0.0232
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	13 (32.5%)	9 (34.6%)	
Patients (%) Without Events (Censored)	27 (67.5%)	17 (65.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.2, NE)	9.7 (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.888 (0.379, 2.080)
p-value			0.7818

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.2758
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	51 (75.0%)	44 (61.1%)	
Patients (%) Without Events (Censored)	17 (25.0%)	28 (38.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 1.0)	1.0 (0.7, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.496 (0.996, 2.246)
p-value			0.0543
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	48 (67.6%)	36 (48.6%)	
Patients (%) Without Events (Censored)	23 (32.4%)	38 (51.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 1.6)	4.9 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.384 (0.897, 2.135)
p-value			0.1343
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.2: Time to the First Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	32 (80.0%)	14 (53.8%)	
Patients (%) Without Events (Censored)	8 (20.0%)	12 (46.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, 0.7)	4.2 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.202 (1.171, 4.142)
p-value			0.0120

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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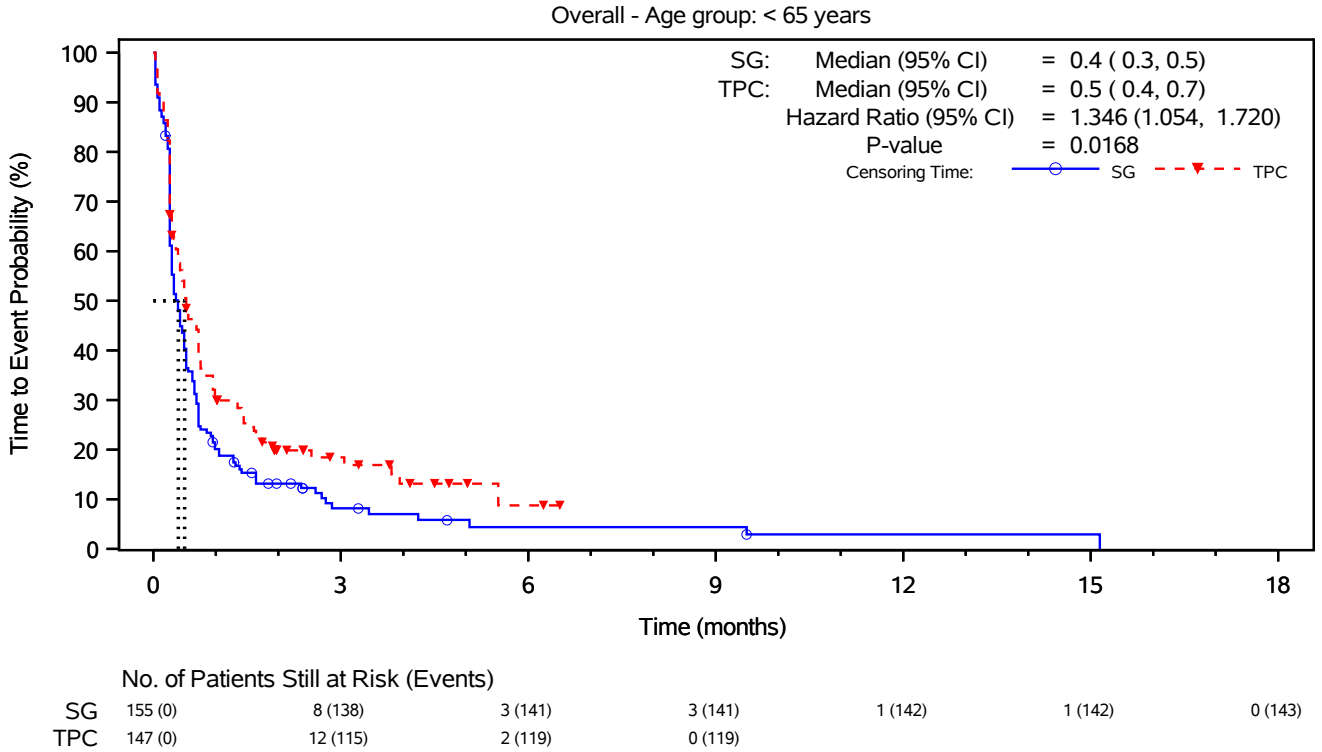
Figure 15.11.4.2.1: KM Plot for Time to the First TEAE of Special Interest by Age Group
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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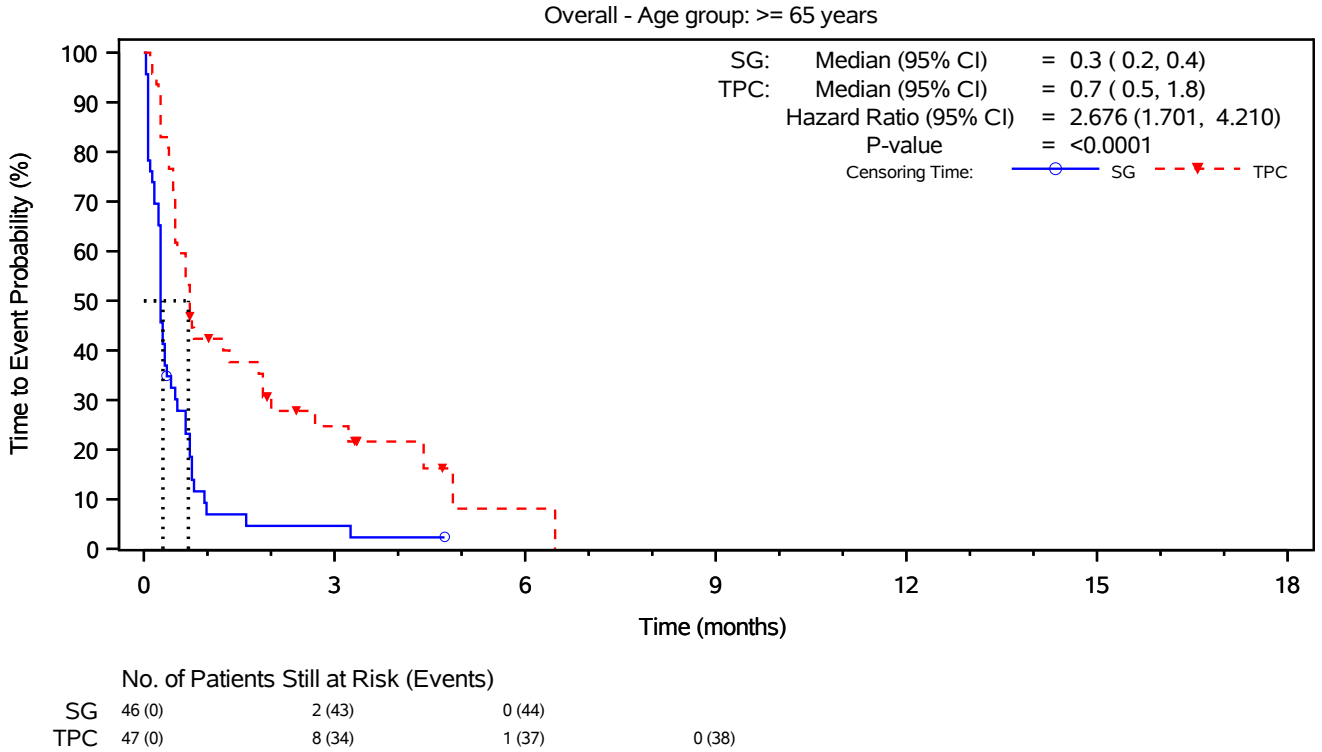
Figure 15.11.4.2.1: KM Plot for Time to the First TEAE of Special Interest by Age Group
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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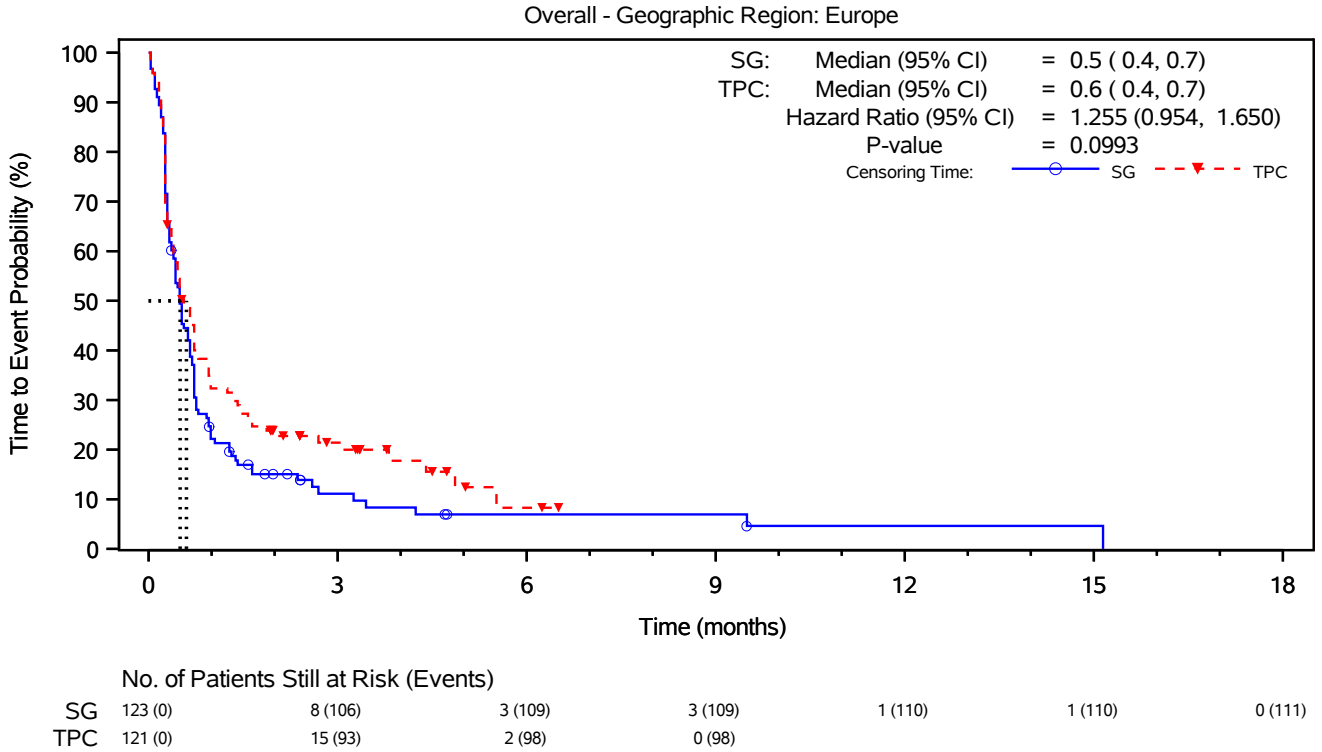
Figure 15.11.4.2.2: KM Plot for Time to the First TEAE of Special Interest by Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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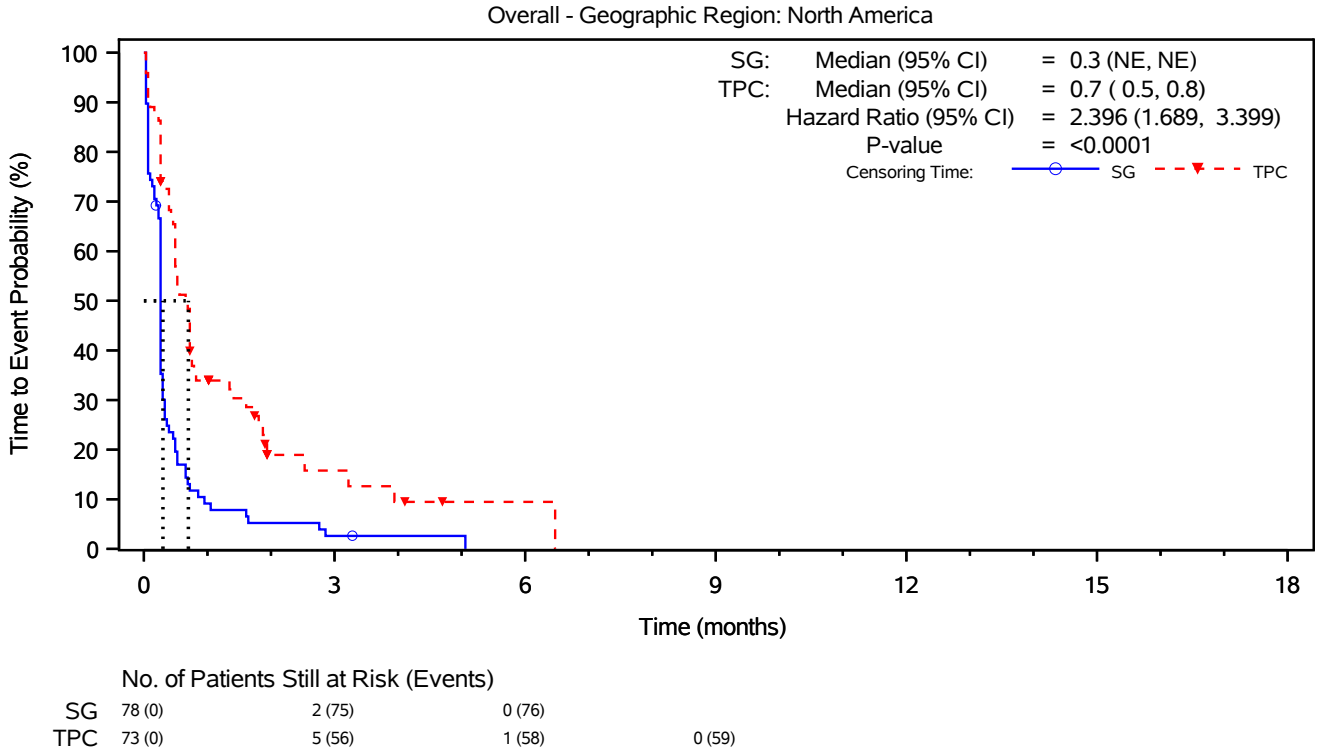
Figure 15.11.4.2.2: KM Plot for Time to the First TEAE of Special Interest by Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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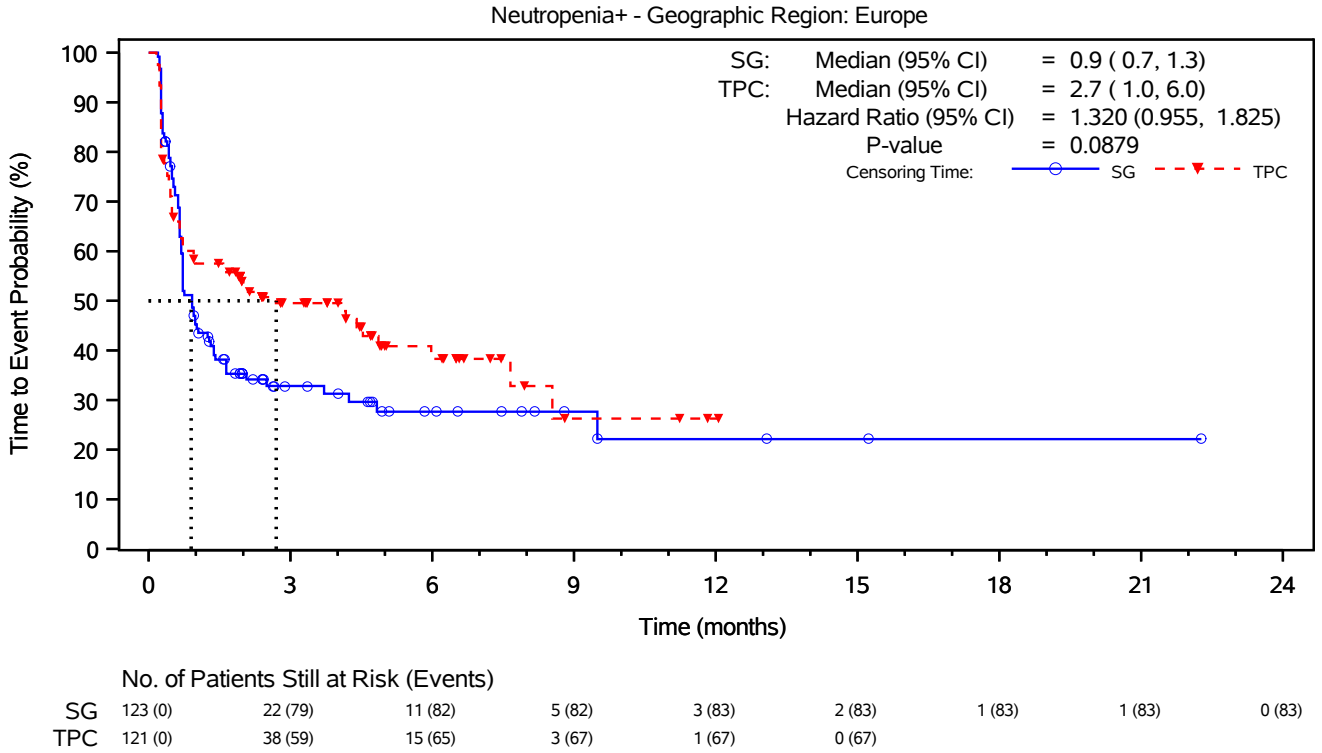
Figure 15.11.4.2.2: KM Plot for Time to the First TEAE of Special Interest by Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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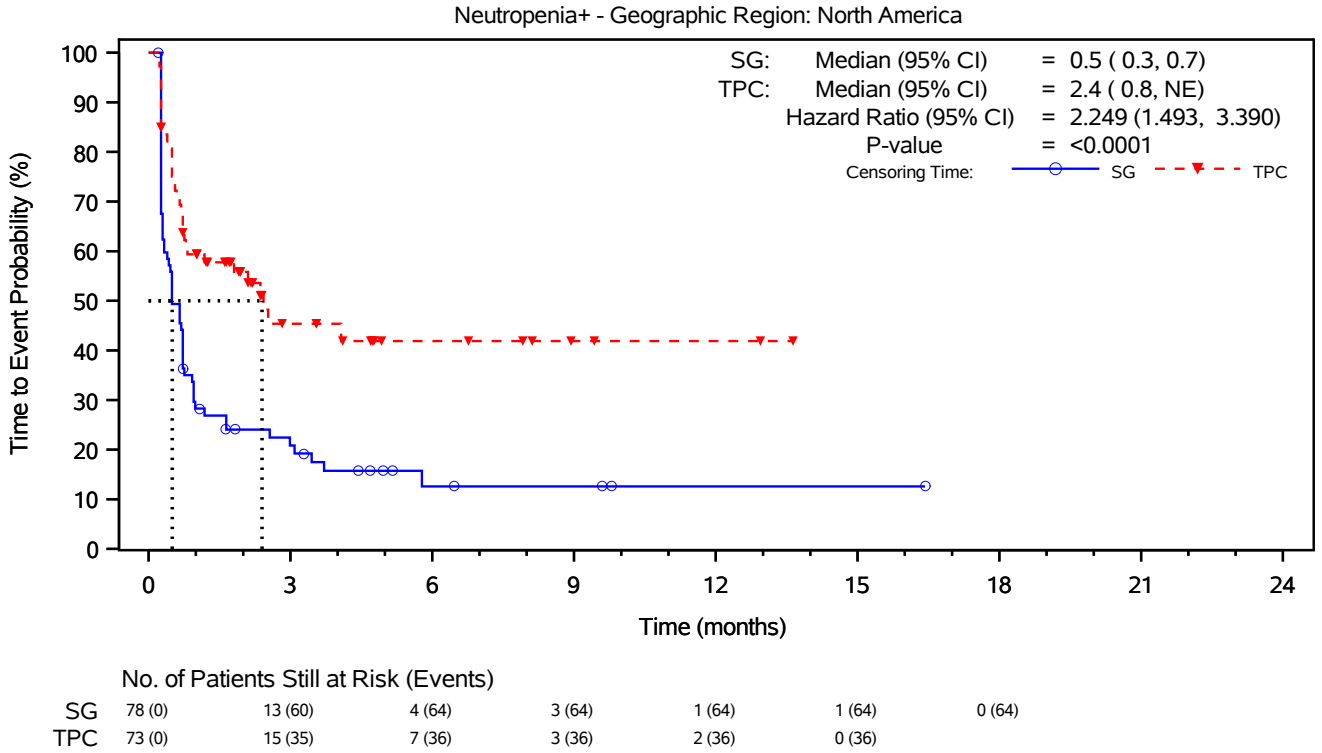
Figure 15.11.4.2.2: KM Plot for Time to the First TEAE of Special Interest by Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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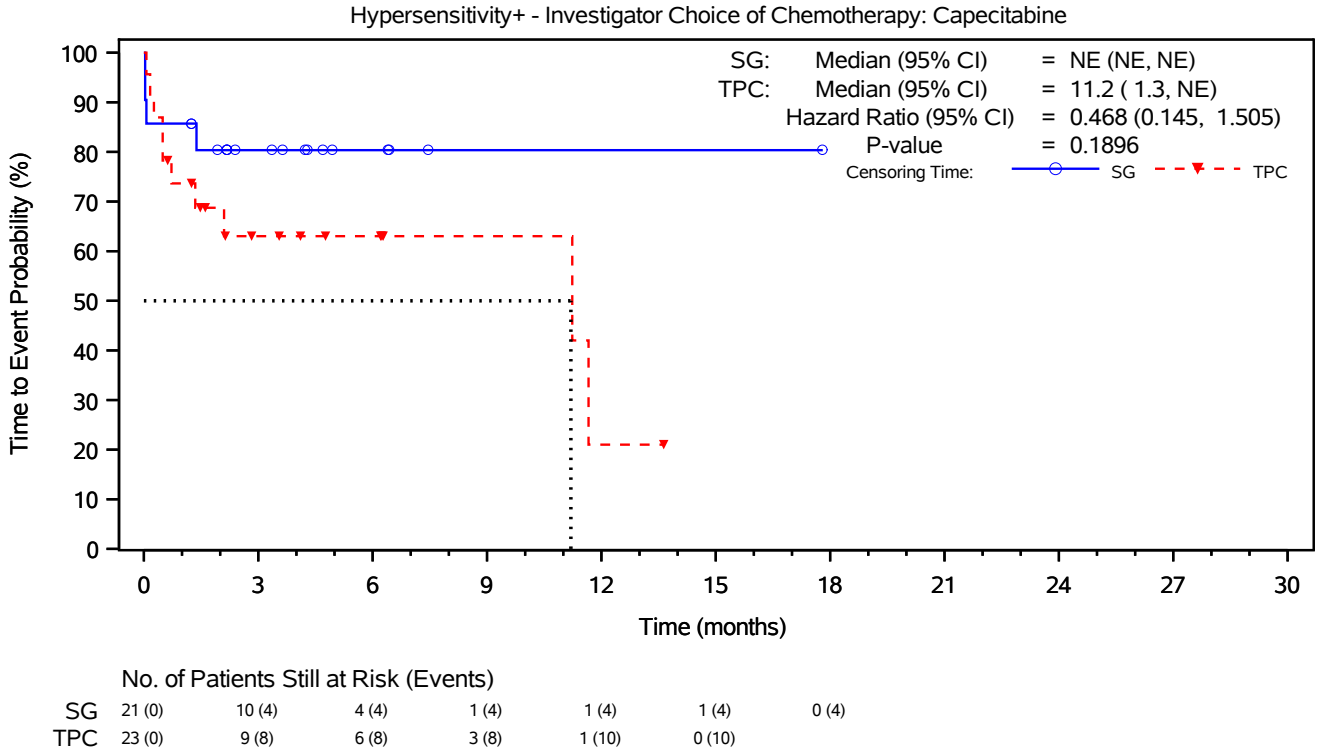
Figure 15.11.4.2.3: KM Plot for Time to the First TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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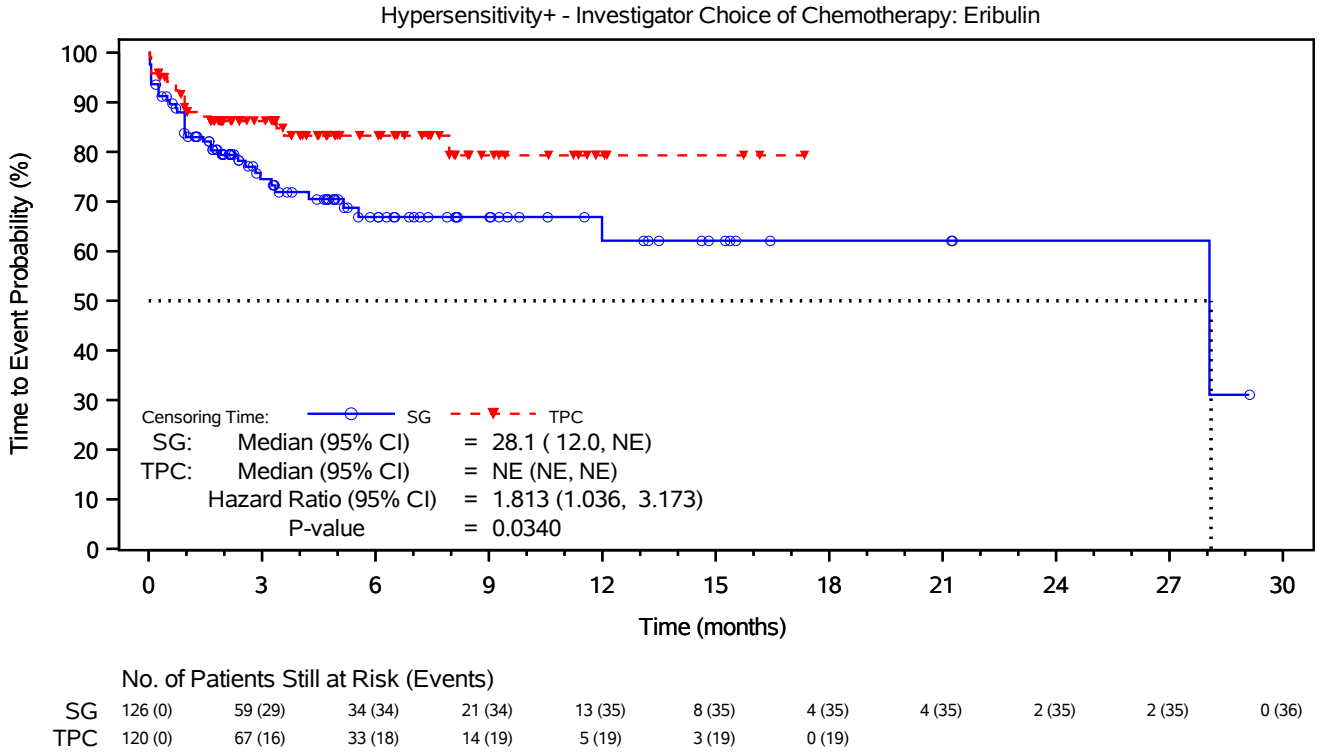
Figure 15.11.4.2.3: KM Plot for Time to the First TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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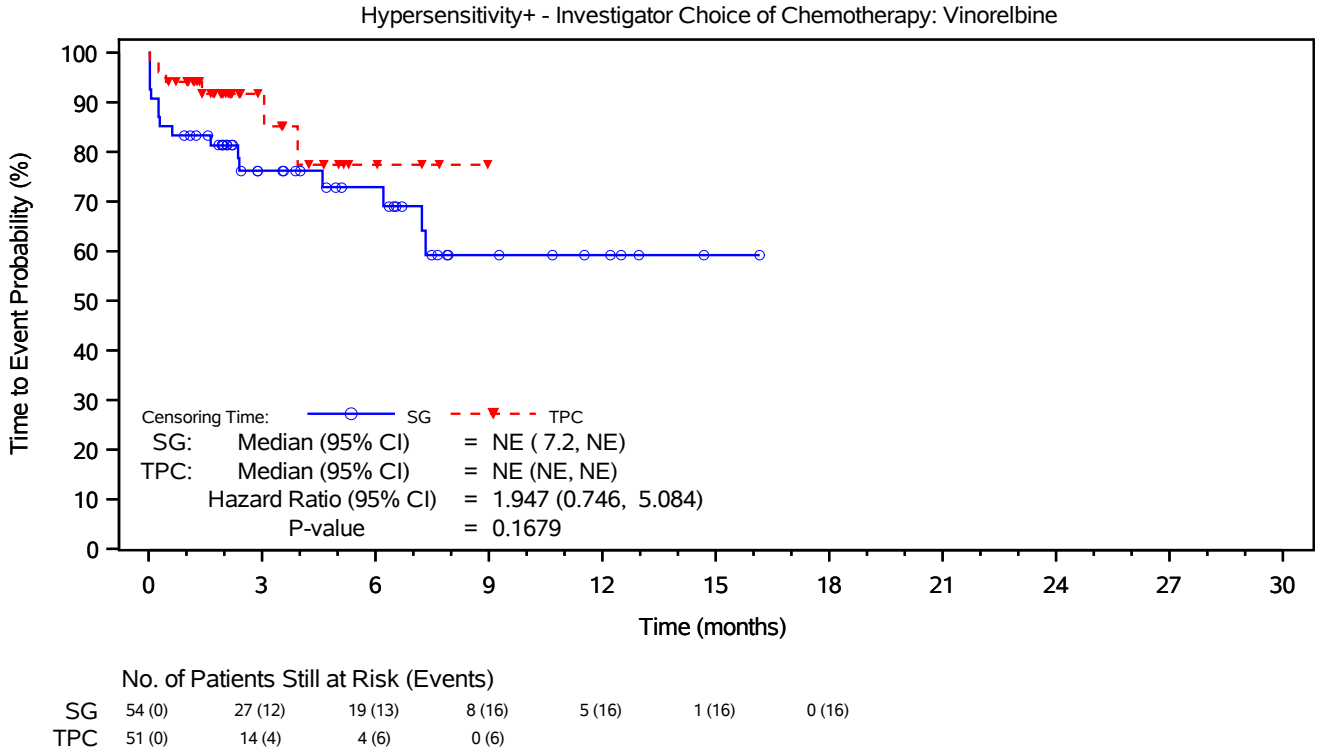
Figure 15.11.4.2.3: KM Plot for Time to the First TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



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NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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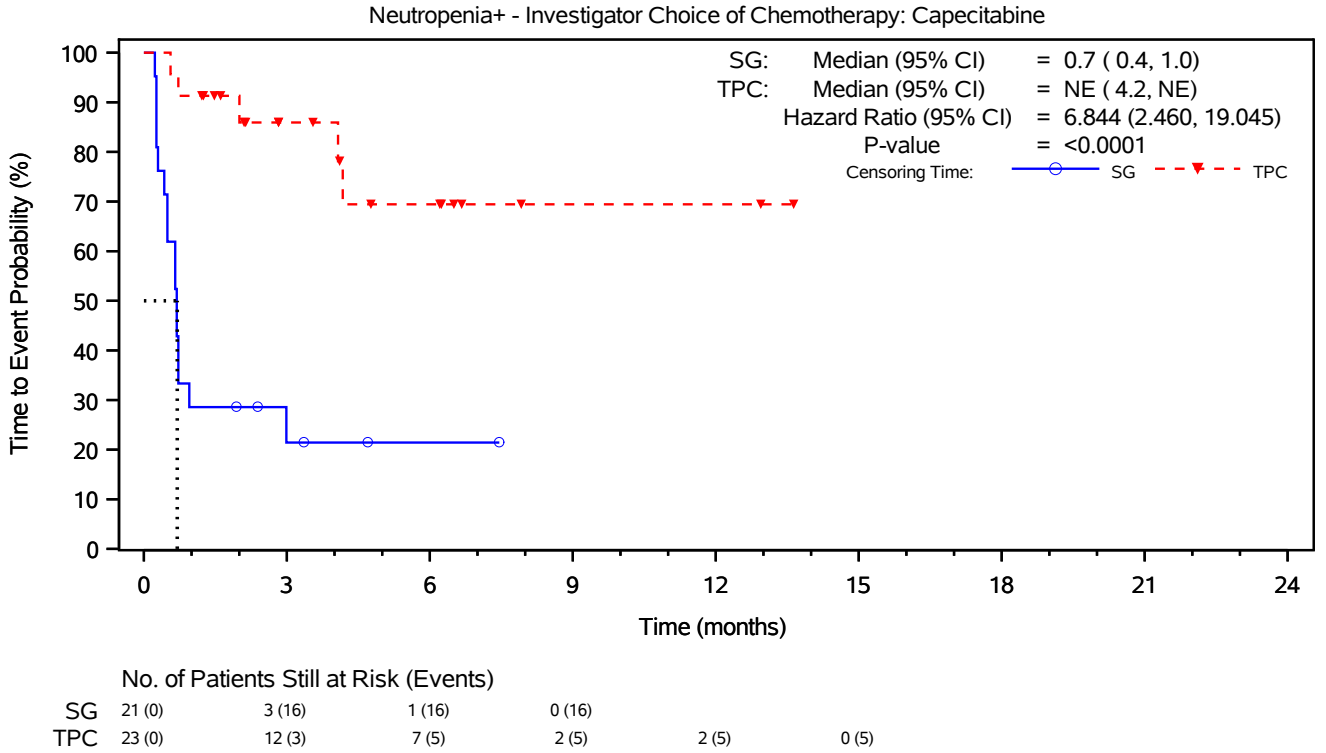
Figure 15.11.4.2.3: KM Plot for Time to the First TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



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NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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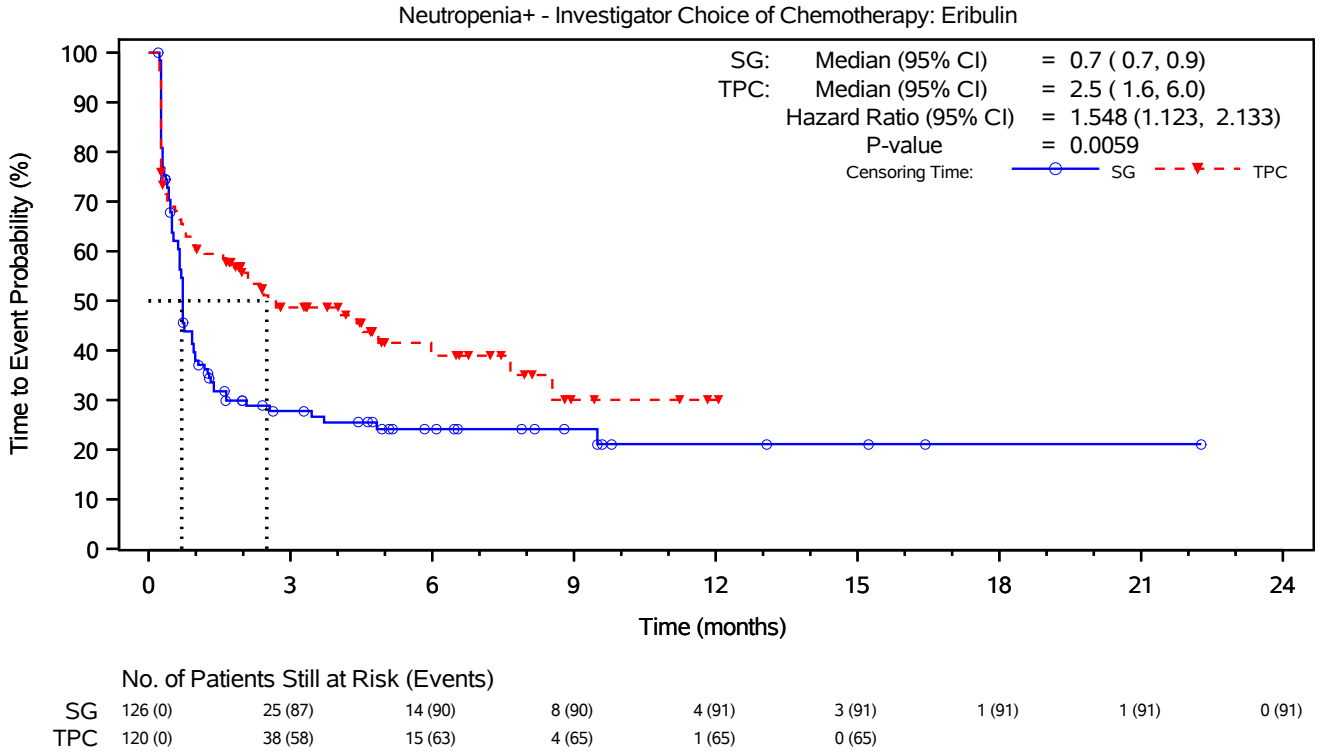
Figure 15.11.4.2.3: KM Plot for Time to the First TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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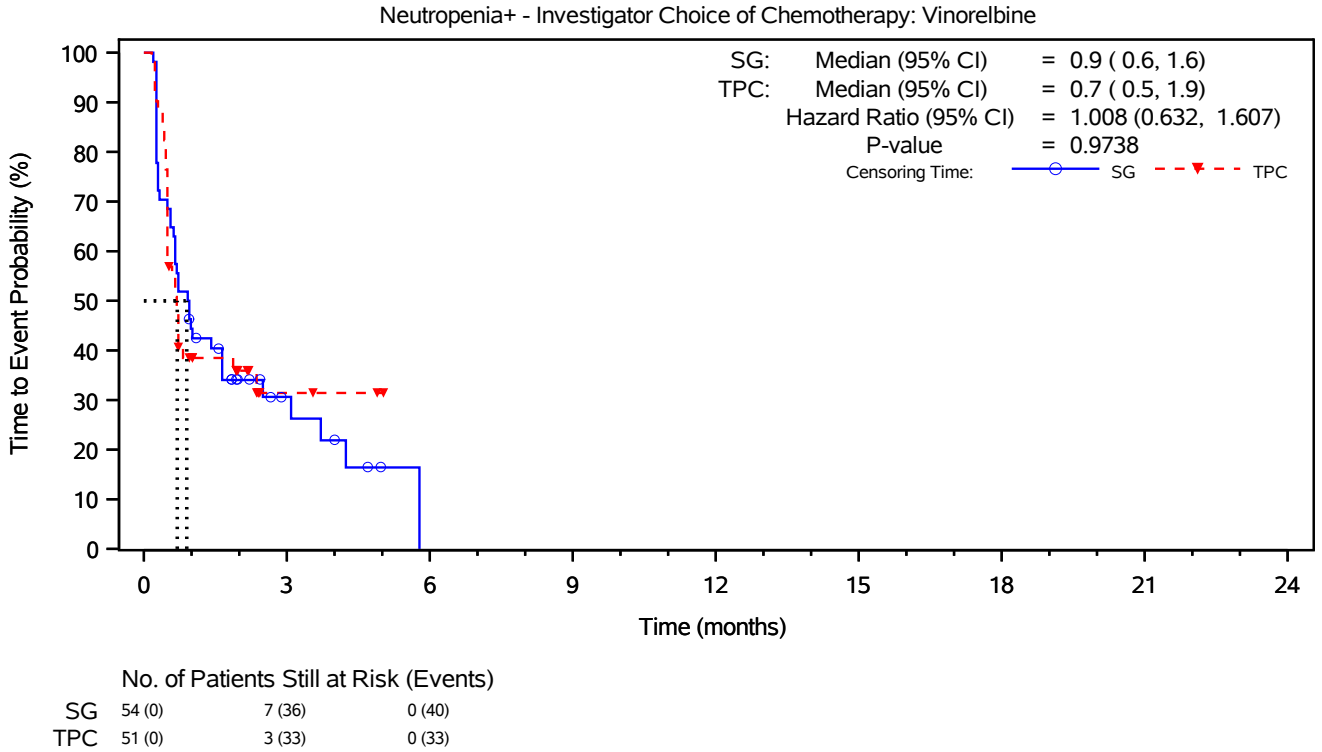
Figure 15.11.4.2.3: KM Plot for Time to the First TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.6338
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	18 (18.9%)	9 (9.8%)	
Patients (%) Without Events (Censored)	77 (81.1%)	83 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.829 (0.820, 4.080)
p-value			0.1356
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	17 (16.0%)	11 (10.8%)	
Patients (%) Without Events (Censored)	89 (84.0%)	91 (89.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.405 (0.657, 3.004)
p-value			0.3783

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.1619
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	5 (5.3%)	3 (3.3%)	
Patients (%) Without Events (Censored)	90 (94.7%)	89 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.587 (0.379, 6.642)
p-value			0.5245
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	3 (2.8%)	7 (6.9%)	
Patients (%) Without Events (Censored)	103 (97.2%)	95 (93.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.395 (0.102, 1.527)
p-value			0.1631

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.3516
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	11 (11.6%)	3 (3.3%)	
Patients (%) Without Events (Censored)	84 (88.4%)	89 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.029 (0.841, 10.914)
p-value			0.0749
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	8 (7.5%)	5 (4.9%)	
Patients (%) Without Events (Censored)	98 (92.5%)	97 (95.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.359 (0.443, 4.172)
p-value			0.5900

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9346
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	6 (6.3%)	5 (5.4%)	
Patients (%) Without Events (Censored)	89 (93.7%)	87 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.137 (0.347, 3.728)
p-value			0.8321
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	8 (7.5%)	7 (6.9%)	
Patients (%) Without Events (Censored)	98 (92.5%)	95 (93.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.074 (0.390, 2.963)
p-value			0.8886

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9835
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	33 (17.2%)	20 (10.8%)	
Patients (%) Without Events (Censored)	159 (82.8%)	166 (89.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.517 (0.869, 2.647)
p-value			0.1406
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	2 (22.2%)	0	
Patients (%) Without Events (Censored)	7 (77.8%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2416

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9996
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	9 (4.7%)	1 (0.5%)	
Patients (%) Without Events (Censored)	183 (95.3%)	185 (99.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			8.658 (1.097, 68.346)
p-value			0.0136
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9999
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	8 (4.2%)	10 (5.4%)	
Patients (%) Without Events (Censored)	184 (95.8%)	176 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.750 (0.296, 1.900)
p-value			0.5427
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9891
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	18 (9.4%)	8 (4.3%)	
Patients (%) Without Events (Censored)	174 (90.6%)	178 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.904 (0.825, 4.397)
p-value			0.1251
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.4795

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9881
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	13 (6.8%)	12 (6.5%)	
Patients (%) Without Events (Censored)	179 (93.2%)	174 (93.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.023 (0.467, 2.243)
p-value			0.9539
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3458

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.0602
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	32 (17.8%)	14 (8.2%)	
Patients (%) Without Events (Censored)	148 (82.2%)	157 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.075 (1.106, 3.893)
p-value			0.0202
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	6 (26.1%)	
Patients (%) Without Events (Censored)	18 (85.7%)	17 (73.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.394 (0.092, 1.688)
p-value			0.1915

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9996
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	9 (5.0%)	1 (0.6%)	
Patients (%) Without Events (Censored)	171 (95.0%)	170 (99.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			8.463 (1.072, 66.811)
p-value			0.0150
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	21 (100.0%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9910
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	8 (4.4%)	7 (4.1%)	
Patients (%) Without Events (Censored)	172 (95.6%)	164 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.060 (0.384, 2.923)
p-value			0.9110
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	0	3 (13.0%)	
Patients (%) Without Events (Censored)	21 (100.0%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0823

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.2850
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	16 (8.9%)	5 (2.9%)	
Patients (%) Without Events (Censored)	164 (91.1%)	166 (97.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.607 (0.951, 7.146)
p-value			0.0532
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	3 (13.0%)	
Patients (%) Without Events (Censored)	18 (85.7%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.898 (0.173, 4.659)
p-value			0.8889

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9879
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	14 (7.8%)	9 (5.3%)	
Patients (%) Without Events (Censored)	166 (92.2%)	162 (94.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.454 (0.630, 3.360)
p-value			0.3784
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	0	3 (13.0%)	
Patients (%) Without Events (Censored)	21 (100.0%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0823

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.2679
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	21 (13.5%)	14 (9.5%)	
Patients (%) Without Events (Censored)	134 (86.5%)	133 (90.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.355 (0.688, 2.666)
p-value			0.3786
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	14 (30.4%)	6 (12.8%)	
Patients (%) Without Events (Censored)	32 (69.6%)	41 (87.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.484 (0.954, 6.470)
p-value			0.0540

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.0635
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	4 (2.6%)	9 (6.1%)	
Patients (%) Without Events (Censored)	151 (97.4%)	138 (93.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.399 (0.123, 1.297)
p-value			0.1136
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	4 (8.7%)	1 (2.1%)	
Patients (%) Without Events (Censored)	42 (91.3%)	46 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.297 (0.480, 38.448)
p-value			0.1549

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.6731
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	9 (5.8%)	4 (2.7%)	
Patients (%) Without Events (Censored)	146 (94.2%)	143 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.917 (0.589, 6.242)
p-value			0.2715
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	10 (21.7%)	4 (8.5%)	
Patients (%) Without Events (Censored)	36 (78.3%)	43 (91.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.467 (0.773, 7.876)
p-value			0.1149

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.1752
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	10 (6.5%)	11 (7.5%)	
Patients (%) Without Events (Censored)	145 (93.5%)	136 (92.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.829 (0.352, 1.952)
p-value			0.6659
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	4 (8.7%)	1 (2.1%)	
Patients (%) Without Events (Censored)	42 (91.3%)	46 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.297 (0.480, 38.448)
p-value			0.1549

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9858
Race: White			
Total Patients	141	132	
Patients (%) With Events	28 (19.9%)	18 (13.6%)	
Patients (%) Without Events (Censored)	113 (80.1%)	114 (86.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.328 (0.733, 2.409)
p-value			0.3483
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2994

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9998
Race: White			
Total Patients	141	132	
Patients (%) With Events	5 (3.5%)	9 (6.8%)	
Patients (%) Without Events (Censored)	136 (96.5%)	123 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.493 (0.165, 1.470)
p-value			0.1958
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9901
Race: White			
Total Patients	141	132	
Patients (%) With Events	16 (11.3%)	7 (5.3%)	
Patients (%) Without Events (Censored)	125 (88.7%)	125 (94.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.787 (0.730, 4.374)
p-value			0.1976
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2994

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9999
Race: White			
Total Patients	141	132	
Patients (%) With Events	10 (7.1%)	11 (8.3%)	
Patients (%) Without Events (Censored)	131 (92.9%)	121 (91.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.816 (0.346, 1.921)
p-value			0.6418
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.7729
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	15 (17.2%)	10 (11.1%)	
Patients (%) Without Events (Censored)	72 (82.8%)	80 (88.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.514 (0.679, 3.375)
p-value			0.3104
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	20 (17.5%)	10 (9.6%)	
Patients (%) Without Events (Censored)	94 (82.5%)	94 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.683 (0.785, 3.605)
p-value			0.1757

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.2289
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	6 (6.9%)	5 (5.6%)	
Patients (%) Without Events (Censored)	81 (93.1%)	85 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.208 (0.369, 3.962)
p-value			0.7557
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	2 (1.8%)	5 (4.8%)	
Patients (%) Without Events (Censored)	112 (98.2%)	99 (95.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.351 (0.068, 1.809)
p-value			0.1906

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9079
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	7 (8.0%)	3 (3.3%)	
Patients (%) Without Events (Censored)	80 (92.0%)	87 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.208 (0.569, 8.567)
p-value			0.2404
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	12 (10.5%)	5 (4.8%)	
Patients (%) Without Events (Censored)	102 (89.5%)	99 (95.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.820 (0.637, 5.203)
p-value			0.2566

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.6013
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	8 (9.2%)	6 (6.7%)	
Patients (%) Without Events (Censored)	79 (90.8%)	84 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.344 (0.466, 3.875)
p-value			0.5839
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	6 (5.3%)	6 (5.8%)	
Patients (%) Without Events (Censored)	108 (94.7%)	98 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.892 (0.288, 2.765)
p-value			0.8439

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.1405
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	23 (18.7%)	10 (8.3%)	
Patients (%) Without Events (Censored)	100 (81.3%)	111 (91.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.301 (1.095, 4.837)
p-value			0.0238
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	12 (15.4%)	10 (13.7%)	
Patients (%) Without Events (Censored)	66 (84.6%)	63 (86.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.910 (0.391, 2.118)
p-value			0.8301

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.1058
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	6 (4.9%)	4 (3.3%)	
Patients (%) Without Events (Censored)	117 (95.1%)	117 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.499 (0.423, 5.314)
p-value			0.5287
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	2 (2.6%)	6 (8.2%)	
Patients (%) Without Events (Censored)	76 (97.4%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.271 (0.054, 1.345)
p-value			0.0875

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.1692
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	14 (11.4%)	4 (3.3%)	
Patients (%) Without Events (Censored)	109 (88.6%)	117 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.297 (1.084, 10.031)
p-value			0.0259
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	5 (6.4%)	4 (5.5%)	
Patients (%) Without Events (Censored)	73 (93.6%)	69 (94.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.801 (0.212, 3.029)
p-value			0.7428

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.1934
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	10 (8.1%)	6 (5.0%)	
Patients (%) Without Events (Censored)	113 (91.9%)	115 (95.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.673 (0.608, 4.605)
p-value			0.3148
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	4 (5.1%)	6 (8.2%)	
Patients (%) Without Events (Censored)	74 (94.9%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.555 (0.156, 1.970)
p-value			0.3578

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.5922
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	21 (18.1%)	11 (9.2%)	
Patients (%) Without Events (Censored)	95 (81.9%)	108 (90.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.843 (0.884, 3.843)
p-value			0.0993
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	14 (17.5%)	9 (12.3%)	
Patients (%) Without Events (Censored)	66 (82.5%)	64 (87.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.357 (0.587, 3.135)
p-value			0.4728

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9817
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	12 (10.3%)	5 (4.2%)	
Patients (%) Without Events (Censored)	104 (89.7%)	114 (95.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.022 (0.703, 5.809)
p-value			0.1825
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	7 (8.8%)	3 (4.1%)	
Patients (%) Without Events (Censored)	73 (91.3%)	70 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.949 (0.504, 7.542)
p-value			0.3244

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.0817
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	10 (8.6%)	5 (4.2%)	
Patients (%) Without Events (Censored)	106 (91.4%)	114 (95.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.079 (0.711, 6.085)
p-value			0.1729
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	4 (5.0%)	7 (9.6%)	
Patients (%) Without Events (Censored)	76 (95.0%)	66 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.491 (0.144, 1.677)
p-value			0.2466

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.4230
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	1 (4.3%)	
Patients (%) Without Events (Censored)	18 (85.7%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.370 (0.350, 32.402)
p-value			0.2636
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	24 (19.0%)	14 (11.7%)	
Patients (%) Without Events (Censored)	102 (81.0%)	106 (88.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.641 (0.849, 3.173)
p-value			0.1371
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	8 (14.8%)	5 (9.8%)	
Patients (%) Without Events (Censored)	46 (85.2%)	46 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.117 (0.352, 3.544)
p-value			0.8532

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9888
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	0	
Patients (%) Without Events (Censored)	20 (95.2%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2953
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	6 (4.8%)	6 (5.0%)	
Patients (%) Without Events (Censored)	120 (95.2%)	114 (95.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.946 (0.305, 2.934)
p-value			0.9255
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	1 (1.9%)	4 (7.8%)	
Patients (%) Without Events (Censored)	53 (98.1%)	47 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.207 (0.023, 1.853)
p-value			0.1191

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9889
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	0	
Patients (%) Without Events (Censored)	20 (95.2%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2963
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	12 (9.5%)	7 (5.8%)	
Patients (%) Without Events (Censored)	114 (90.5%)	113 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.554 (0.611, 3.950)
p-value			0.3516
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	6 (11.1%)	1 (2.0%)	
Patients (%) Without Events (Censored)	48 (88.9%)	50 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.895 (0.451, 33.619)
p-value			0.1830

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9865
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	0	
Patients (%) Without Events (Censored)	19 (90.5%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1341
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	10 (7.9%)	8 (6.7%)	
Patients (%) Without Events (Censored)	116 (92.1%)	112 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.183 (0.467, 2.997)
p-value			0.7201
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	2 (3.7%)	4 (7.8%)	
Patients (%) Without Events (Censored)	52 (96.3%)	47 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.428 (0.078, 2.344)
p-value			0.3140

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9848
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	2 (14.3%)	
Patients (%) Without Events (Censored)	13 (100.0%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (1.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1303
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	32 (17.7%)	18 (10.2%)	
Patients (%) Without Events (Censored)	149 (82.3%)	158 (89.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.659 (0.930, 2.960)
p-value			0.0838

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9995
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	9 (5.0%)	1 (0.6%)	
Patients (%) Without Events (Censored)	172 (95.0%)	175 (99.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			8.781 (1.112, 69.319)
p-value			0.0128

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9920
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2770
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	7 (3.9%)	9 (5.1%)	
Patients (%) Without Events (Censored)	174 (96.1%)	167 (94.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.742 (0.276, 1.993)
p-value			0.5526

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9890
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3173
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	17 (9.4%)	7 (4.0%)	
Patients (%) Without Events (Censored)	164 (90.6%)	169 (96.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.065 (0.853, 4.999)
p-value			0.1006

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9902
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2770
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	13 (7.2%)	11 (6.3%)	
Patients (%) Without Events (Censored)	168 (92.8%)	165 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.137 (0.509, 2.538)
p-value			0.7536

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.5183
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	29 (16.4%)	18 (10.5%)	
Patients (%) Without Events (Censored)	148 (83.6%)	153 (89.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.493 (0.828, 2.692)
p-value			0.1810
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	6 (25.0%)	2 (8.7%)	
Patients (%) Without Events (Censored)	18 (75.0%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.314 (0.464, 11.536)
p-value			0.2924

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9895
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	7 (4.0%)	10 (5.8%)	
Patients (%) Without Events (Censored)	170 (96.0%)	161 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.655 (0.249, 1.720)
p-value			0.3863
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	1 (4.2%)	0	
Patients (%) Without Events (Censored)	23 (95.8%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3276

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.6602
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	15 (8.5%)	7 (4.1%)	
Patients (%) Without Events (Censored)	162 (91.5%)	164 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.825 (0.741, 4.498)
p-value			0.1845
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	4 (16.7%)	1 (4.3%)	
Patients (%) Without Events (Censored)	20 (83.3%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.802 (0.311, 25.244)
p-value			0.3374

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9872
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	12 (6.8%)	12 (7.0%)	
Patients (%) Without Events (Censored)	165 (93.2%)	159 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.941 (0.423, 2.096)
p-value			0.8815
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	2 (8.3%)	0	
Patients (%) Without Events (Censored)	22 (91.7%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1617

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.5092
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	22 (18.0%)	15 (11.6%)	
Patients (%) Without Events (Censored)	100 (82.0%)	114 (88.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.441 (0.745, 2.785)
p-value			0.2752
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	13 (16.5%)	5 (7.7%)	
Patients (%) Without Events (Censored)	66 (83.5%)	60 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.094 (0.746, 5.881)
p-value			0.1513

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.2566
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	4 (3.3%)	8 (6.2%)	
Patients (%) Without Events (Censored)	118 (96.7%)	121 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.497 (0.150, 1.652)
p-value			0.2447
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	4 (5.1%)	2 (3.1%)	
Patients (%) Without Events (Censored)	75 (94.9%)	63 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.686 (0.309, 9.206)
p-value			0.5430

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.3301
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	10 (8.2%)	6 (4.7%)	
Patients (%) Without Events (Censored)	112 (91.8%)	123 (95.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.497 (0.539, 4.162)
p-value			0.4371
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	9 (11.4%)	2 (3.1%)	
Patients (%) Without Events (Censored)	70 (88.6%)	63 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.431 (0.741, 15.897)
p-value			0.0935

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.7190
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	9 (7.4%)	9 (7.0%)	
Patients (%) Without Events (Censored)	113 (92.6%)	120 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.011 (0.401, 2.547)
p-value			0.9814
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	5 (6.3%)	3 (4.6%)	
Patients (%) Without Events (Censored)	74 (93.7%)	62 (95.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.408 (0.336, 5.892)
p-value			0.6391

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9879
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	11 (16.2%)	8 (11.1%)	
Patients (%) Without Events (Censored)	57 (83.8%)	64 (88.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.478 (0.594, 3.678)
p-value			0.4031
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	12 (16.9%)	8 (10.8%)	
Patients (%) Without Events (Censored)	59 (83.1%)	66 (89.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.319 (0.536, 3.247)
p-value			0.5456
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	9 (22.5%)	4 (15.4%)	
Patients (%) Without Events (Censored)	31 (77.5%)	22 (84.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.438 (0.442, 4.674)
p-value			0.5457

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.8303
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	4 (5.9%)	2 (2.8%)	
Patients (%) Without Events (Censored)	64 (94.1%)	70 (97.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.087 (0.381, 11.425)
p-value			0.3868
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	8 (11.3%)	4 (5.4%)	
Patients (%) Without Events (Censored)	63 (88.7%)	70 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.555 (0.461, 5.249)
p-value			0.4736
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	5 (12.5%)	2 (7.7%)	
Patients (%) Without Events (Censored)	35 (87.5%)	24 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.532 (0.296, 7.935)
p-value			0.6083

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.8161
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	5 (7.4%)	5 (6.9%)	
Patients (%) Without Events (Censored)	63 (92.6%)	67 (93.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.063 (0.308, 3.671)
p-value			0.9235
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	5 (7.0%)	4 (5.4%)	
Patients (%) Without Events (Censored)	66 (93.0%)	70 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.242 (0.333, 4.633)
p-value			0.7478
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.4: Time to the First Serious Treatment-Emergent Adverse Event (TEAE) of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	4 (10.0%)	3 (11.5%)	
Patients (%) Without Events (Censored)	36 (90.0%)	23 (88.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.838 (0.187, 3.743)
p-value			0.8163

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.0797
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	62 (65.3%)	34 (37.0%)	
Patients (%) Without Events (Censored)	33 (34.7%)	58 (63.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.7, 2.5)	NE (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.061 (1.355, 3.134)
p-value			0.0005
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	63 (59.4%)	52 (51.0%)	
Patients (%) Without Events (Censored)	43 (40.6%)	50 (49.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.9, 6.3)	3.1 (2.1, 9.6)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.267 (0.877, 1.829)
p-value			0.2172

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.7656
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	8 (8.4%)	1 (1.1%)	
Patients (%) Without Events (Censored)	87 (91.6%)	91 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.548 (0.942, 60.448)
p-value			0.0250
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	11 (10.4%)	2 (2.0%)	
Patients (%) Without Events (Censored)	95 (89.6%)	100 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.188 (1.150, 23.412)
p-value			0.0168

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.1207
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	7 (7.4%)	3 (3.3%)	
Patients (%) Without Events (Censored)	88 (92.6%)	89 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.260 (0.584, 8.741)
p-value			0.2251
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	5 (4.7%)	8 (7.8%)	
Patients (%) Without Events (Censored)	101 (95.3%)	94 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.558 (0.182, 1.707)
p-value			0.2998

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.1969
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	11 (11.6%)	2 (2.2%)	
Patients (%) Without Events (Censored)	84 (88.4%)	90 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.624 (1.020, 20.959)
p-value			0.0291
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	10 (9.4%)	6 (5.9%)	
Patients (%) Without Events (Censored)	96 (90.6%)	96 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.297 (0.464, 3.626)
p-value			0.6186

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.0303
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	57 (60.0%)	30 (32.6%)	
Patients (%) Without Events (Censored)	38 (40.0%)	62 (67.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, 3.7)	NE (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.147 (1.378, 3.344)
p-value			0.0005
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	54 (50.9%)	47 (46.1%)	
Patients (%) Without Events (Censored)	52 (49.1%)	55 (53.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (1.0, NE)	8.3 (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.122 (0.758, 1.659)
p-value			0.5894

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.4202
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	118 (61.5%)	83 (44.6%)	
Patients (%) Without Events (Censored)	74 (38.5%)	103 (55.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.9, 2.3)	5.8 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.542 (1.164, 2.043)
p-value			0.0023
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	7 (77.8%)	3 (37.5%)	
Patients (%) Without Events (Censored)	2 (22.2%)	5 (62.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, NE)	NE (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.861 (0.727, 11.265)
p-value			0.1188

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9994
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	19 (9.9%)	3 (1.6%)	
Patients (%) Without Events (Censored)	173 (90.1%)	183 (98.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.974 (1.766, 20.210)
p-value			0.0011
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			1.0000
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	12 (6.3%)	11 (5.9%)	
Patients (%) Without Events (Censored)	180 (93.8%)	175 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.019 (0.450, 2.311)
p-value			0.9641
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9890
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	20 (10.4%)	8 (4.3%)	
Patients (%) Without Events (Censored)	172 (89.6%)	178 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.081 (0.911, 4.752)
p-value			0.0756
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.4795

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.9921
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	5 (2.6%)	7 (3.8%)	
Patients (%) Without Events (Censored)	187 (97.4%)	179 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.565 (0.178, 1.794)
p-value			0.3268
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.4142

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.7218
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	106 (55.2%)	74 (39.8%)	
Patients (%) Without Events (Censored)	86 (44.8%)	112 (60.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (1.0, 4.6)	9.6 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.504 (1.117, 2.025)
p-value			0.0068
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	5 (55.6%)	3 (37.5%)	
Patients (%) Without Events (Censored)	4 (44.4%)	5 (62.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, NE)	NE (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.279 (0.538, 9.644)
p-value			0.2553

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.2176
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	114 (63.3%)	74 (43.3%)	
Patients (%) Without Events (Censored)	66 (36.7%)	97 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.9, 2.2)	8.3 (3.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.676 (1.250, 2.246)
p-value			0.0005
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	11 (52.4%)	12 (52.2%)	
Patients (%) Without Events (Censored)	10 (47.6%)	11 (47.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (0.5, NE)	2.3 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.896 (0.391, 2.052)
p-value			0.7921

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9909
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	16 (8.9%)	3 (1.8%)	
Patients (%) Without Events (Censored)	164 (91.1%)	168 (98.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.860 (1.414, 16.707)
p-value			0.0055
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	0	
Patients (%) Without Events (Censored)	18 (85.7%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0738

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.3158
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	11 (6.1%)	8 (4.7%)	
Patients (%) Without Events (Censored)	169 (93.9%)	163 (95.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.261 (0.507, 3.135)
p-value			0.6173
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	3 (13.0%)	
Patients (%) Without Events (Censored)	20 (95.2%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.349 (0.036, 3.358)
p-value			0.3399

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.5873
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	18 (10.0%)	6 (3.5%)	
Patients (%) Without Events (Censored)	162 (90.0%)	165 (96.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.409 (0.950, 6.106)
p-value			0.0561
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	2 (8.7%)	
Patients (%) Without Events (Censored)	18 (85.7%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.344 (0.214, 8.460)
p-value			0.7599

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.9921
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	5 (2.8%)	7 (4.1%)	
Patients (%) Without Events (Censored)	175 (97.2%)	164 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.530 (0.167, 1.683)
p-value			0.2737
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	0	
Patients (%) Without Events (Censored)	20 (95.2%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2781

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.1157
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	104 (57.8%)	67 (39.2%)	
Patients (%) Without Events (Censored)	76 (42.2%)	104 (60.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.9, 3.7)	9.6 (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.642 (1.208, 2.233)
p-value			0.0015
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	7 (33.3%)	10 (43.5%)	
Patients (%) Without Events (Censored)	14 (66.7%)	13 (56.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.7, NE)	2.4 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.700 (0.265, 1.851)
p-value			0.4682

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9070
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	95 (61.3%)	63 (42.9%)	
Patients (%) Without Events (Censored)	60 (38.7%)	84 (57.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.9, 2.5)	8.3 (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.566 (1.138, 2.154)
p-value			0.0056
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	30 (65.2%)	23 (48.9%)	
Patients (%) Without Events (Censored)	16 (34.8%)	24 (51.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.6, 6.3)	3.8 (1.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.642 (0.951, 2.833)
p-value			0.0719

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.7872
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	12 (7.7%)	2 (1.4%)	
Patients (%) Without Events (Censored)	143 (92.3%)	145 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.186 (1.157, 23.245)
p-value			0.0165
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	7 (15.2%)	1 (2.1%)	
Patients (%) Without Events (Censored)	39 (84.8%)	46 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.785 (0.957, 63.300)
p-value			0.0230

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.0750
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	7 (4.5%)	10 (6.8%)	
Patients (%) Without Events (Censored)	148 (95.5%)	137 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.622 (0.236, 1.634)
p-value			0.3295
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	5 (10.9%)	1 (2.1%)	
Patients (%) Without Events (Censored)	41 (89.1%)	46 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.438 (0.635, 46.551)
p-value			0.0824

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.8492
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	10 (6.5%)	3 (2.0%)	
Patients (%) Without Events (Censored)	145 (93.5%)	144 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.649 (0.722, 9.718)
p-value			0.1273
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	11 (23.9%)	5 (10.6%)	
Patients (%) Without Events (Censored)	35 (76.1%)	42 (89.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.231 (0.774, 6.431)
p-value			0.1270

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.8467
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	88 (56.8%)	58 (39.5%)	
Patients (%) Without Events (Censored)	67 (43.2%)	89 (60.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (1.0, 4.6)	9.6 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.540 (1.104, 2.146)
p-value			0.0106
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	23 (50.0%)	19 (40.4%)	
Patients (%) Without Events (Censored)	23 (50.0%)	28 (59.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (0.9, NE)	6.0 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.427 (0.776, 2.624)
p-value			0.2549

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.9084
Race: White			
Total Patients	141	132	
Patients (%) With Events	89 (63.1%)	62 (47.0%)	
Patients (%) Without Events (Censored)	52 (36.9%)	70 (53.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.3)	4.4 (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.499 (1.084, 2.075)
p-value			0.0140
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	8 (61.5%)	7 (43.8%)	
Patients (%) Without Events (Censored)	5 (38.5%)	9 (56.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.567 (0.566, 4.340)
p-value			0.4120

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9997
Race: White			
Total Patients	141	132	
Patients (%) With Events	11 (7.8%)	2 (1.5%)	
Patients (%) Without Events (Censored)	130 (92.2%)	130 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.774 (1.055, 21.601)
p-value			0.0251
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9999
Race: White			
Total Patients	141	132	
Patients (%) With Events	8 (5.7%)	10 (7.6%)	
Patients (%) Without Events (Censored)	133 (94.3%)	122 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.702 (0.277, 1.779)
p-value			0.4546
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9895
Race: White			
Total Patients	141	132	
Patients (%) With Events	19 (13.5%)	8 (6.1%)	
Patients (%) Without Events (Censored)	122 (86.5%)	124 (93.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.802 (0.780, 4.160)
p-value			0.1621
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2994

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.9999
Race: White			
Total Patients	141	132	
Patients (%) With Events	6 (4.3%)	7 (5.3%)	
Patients (%) Without Events (Censored)	135 (95.7%)	125 (94.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.611 (0.203, 1.838)
p-value			0.3758
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.8898
Race: White			
Total Patients	141	132	
Patients (%) With Events	79 (56.0%)	54 (40.9%)	
Patients (%) Without Events (Censored)	62 (44.0%)	78 (59.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.9, 4.6)	9.6 (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.495 (1.057, 2.114)
p-value			0.0223
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	7 (53.8%)	7 (43.8%)	
Patients (%) Without Events (Censored)	6 (46.2%)	9 (56.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.7 (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.401 (0.490, 4.009)
p-value			0.5673

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.7197
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	55 (63.2%)	41 (45.6%)	
Patients (%) Without Events (Censored)	32 (36.8%)	49 (54.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 3.7)	5.8 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.481 (0.987, 2.221)
p-value			0.0549
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	70 (61.4%)	45 (43.3%)	
Patients (%) Without Events (Censored)	44 (38.6%)	59 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.9, 2.6)	3.8 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.673 (1.149, 2.434)
p-value			0.0068

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.3885
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	7 (8.0%)	2 (2.2%)	
Patients (%) Without Events (Censored)	80 (92.0%)	88 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.612 (0.750, 17.403)
p-value			0.0869
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	12 (10.5%)	1 (1.0%)	
Patients (%) Without Events (Censored)	102 (89.5%)	103 (99.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			10.500 (1.364, 80.844)
p-value			0.0049

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.4242
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	7 (8.0%)	5 (5.6%)	
Patients (%) Without Events (Censored)	80 (92.0%)	85 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.427 (0.453, 4.497)
p-value			0.5440
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	5 (4.4%)	6 (5.8%)	
Patients (%) Without Events (Censored)	109 (95.6%)	98 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.715 (0.218, 2.344)
p-value			0.5787

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.8877
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	8 (9.2%)	3 (3.3%)	
Patients (%) Without Events (Censored)	79 (90.8%)	87 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.564 (0.678, 9.695)
p-value			0.1505
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	13 (11.4%)	5 (4.8%)	
Patients (%) Without Events (Censored)	101 (88.6%)	99 (95.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.937 (0.685, 5.478)
p-value			0.2049

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.7984
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	52 (59.8%)	36 (40.0%)	
Patients (%) Without Events (Censored)	35 (40.2%)	54 (60.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.7, 4.8)	8.3 (4.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.566 (1.022, 2.398)
p-value			0.0364
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	59 (51.8%)	41 (39.4%)	
Patients (%) Without Events (Censored)	55 (48.2%)	63 (60.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.5 (1.0, NE)	NE (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.481 (0.994, 2.206)
p-value			0.0553

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.1245
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	72 (58.5%)	57 (47.1%)	
Patients (%) Without Events (Censored)	51 (41.5%)	64 (52.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.5 (1.0, 4.8)	4.6 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.339 (0.946, 1.897)
p-value			0.0957
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	53 (67.9%)	29 (39.7%)	
Patients (%) Without Events (Censored)	25 (32.1%)	44 (60.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.5, 1.9)	NE (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.073 (1.317, 3.262)
p-value			0.0014

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.3090
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	12 (9.8%)	1 (0.8%)	
Patients (%) Without Events (Censored)	111 (90.2%)	120 (99.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			11.458 (1.488, 88.251)
p-value			0.0031
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	7 (9.0%)	2 (2.7%)	
Patients (%) Without Events (Censored)	71 (91.0%)	71 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.138 (0.651, 15.131)
p-value			0.1332

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.1039
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	9 (7.3%)	5 (4.1%)	
Patients (%) Without Events (Censored)	114 (92.7%)	116 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.788 (0.599, 5.337)
p-value			0.2916
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	3 (3.8%)	6 (8.2%)	
Patients (%) Without Events (Censored)	75 (96.2%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.414 (0.103, 1.659)
p-value			0.1995

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.1063
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	14 (11.4%)	3 (2.5%)	
Patients (%) Without Events (Censored)	109 (88.6%)	118 (97.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.228 (1.211, 14.760)
p-value			0.0140
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	7 (9.0%)	5 (6.8%)	
Patients (%) Without Events (Censored)	71 (91.0%)	68 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.983 (0.308, 3.137)
p-value			0.9776

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.0192
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	62 (50.4%)	54 (44.6%)	
Patients (%) Without Events (Censored)	61 (49.6%)	67 (55.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.8 (1.0, NE)	8.3 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.161 (0.806, 1.673)
p-value			0.4169
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	49 (62.8%)	23 (31.5%)	
Patients (%) Without Events (Censored)	29 (37.2%)	50 (68.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.5, 2.6)	NE (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.396 (1.459, 3.936)
p-value			0.0004

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.3165
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	70 (60.3%)	54 (45.4%)	
Patients (%) Without Events (Censored)	46 (39.7%)	65 (54.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.9, 3.8)	4.4 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.400 (0.981, 1.998)
p-value			0.0588
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	53 (66.3%)	32 (43.8%)	
Patients (%) Without Events (Censored)	27 (33.8%)	41 (56.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 1.9)	5.8 (1.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.900 (1.224, 2.949)
p-value			0.0042

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9673
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	12 (10.3%)	2 (1.7%)	
Patients (%) Without Events (Censored)	104 (89.7%)	117 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.165 (1.379, 27.567)
p-value			0.0065
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	7 (8.8%)	1 (1.4%)	
Patients (%) Without Events (Censored)	73 (91.3%)	72 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.142 (0.756, 49.935)
p-value			0.0524

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.4058
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	7 (6.0%)	5 (4.2%)	
Patients (%) Without Events (Censored)	109 (94.0%)	114 (95.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.427 (0.453, 4.499)
p-value			0.5439
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	5 (6.3%)	6 (8.2%)	
Patients (%) Without Events (Censored)	75 (93.8%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.708 (0.216, 2.321)
p-value			0.5679

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.5535
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	13 (11.2%)	4 (3.4%)	
Patients (%) Without Events (Censored)	103 (88.8%)	115 (96.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.691 (0.863, 8.393)
p-value			0.0765
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	8 (10.0%)	4 (5.5%)	
Patients (%) Without Events (Censored)	72 (90.0%)	69 (94.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.676 (0.505, 5.570)
p-value			0.3937

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.5636
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	61 (52.6%)	46 (38.7%)	
Patients (%) Without Events (Censored)	55 (47.4%)	73 (61.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (1.0, 6.9)	8.3 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.395 (0.951, 2.048)
p-value			0.0814
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	48 (60.0%)	31 (42.5%)	
Patients (%) Without Events (Censored)	32 (40.0%)	42 (57.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.6)	NE (1.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.698 (1.081, 2.669)
p-value			0.0232

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.0058
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	14 (66.7%)	3 (13.0%)	
Patients (%) Without Events (Censored)	7 (33.3%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.6, 4.8)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.552 (2.156, 26.458)
p-value			0.0002
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	81 (64.3%)	59 (49.2%)	
Patients (%) Without Events (Censored)	45 (35.7%)	61 (50.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.2)	4.4 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.473 (1.052, 2.062)
p-value			0.0213
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	30 (55.6%)	24 (47.1%)	
Patients (%) Without Events (Censored)	24 (44.4%)	27 (52.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (0.9, NE)	2.4 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.112 (0.646, 1.916)
p-value			0.7214

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.6621
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	2 (8.7%)	
Patients (%) Without Events (Censored)	19 (90.5%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.121 (0.158, 7.963)
p-value			0.9089
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	14 (11.1%)	0	
Patients (%) Without Events (Censored)	112 (88.9%)	120 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0002
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (5.6%)	1 (2.0%)	
Patients (%) Without Events (Censored)	51 (94.4%)	50 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.303 (0.237, 22.397)
p-value			0.4599

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9881
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	0	
Patients (%) Without Events (Censored)	20 (95.2%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2953
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	8 (6.3%)	7 (5.8%)	
Patients (%) Without Events (Censored)	118 (93.7%)	113 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.083 (0.393, 2.986)
p-value			0.8773
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (5.6%)	4 (7.8%)	
Patients (%) Without Events (Censored)	51 (94.4%)	47 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.536 (0.118, 2.434)
p-value			0.4124

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.5033
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	1 (4.3%)	
Patients (%) Without Events (Censored)	20 (95.2%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.093 (0.068, 17.478)
p-value			0.9498
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	14 (11.1%)	6 (5.0%)	
Patients (%) Without Events (Censored)	112 (88.9%)	114 (95.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.112 (0.810, 5.510)
p-value			0.1179
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	6 (11.1%)	1 (2.0%)	
Patients (%) Without Events (Censored)	48 (88.9%)	50 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.331 (0.378, 29.341)
p-value			0.2518

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9747
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	13 (61.9%)	0	
Patients (%) Without Events (Censored)	8 (38.1%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	69 (54.8%)	53 (44.2%)	
Patients (%) Without Events (Censored)	57 (45.2%)	67 (55.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.9, NE)	8.3 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.346 (0.940, 1.928)
p-value			0.0978
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	29 (53.7%)	24 (47.1%)	
Patients (%) Without Events (Censored)	25 (46.3%)	27 (52.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (0.9, NE)	2.4 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.086 (0.628, 1.877)
p-value			0.7932

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.6473
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	7 (53.8%)	6 (42.9%)	
Patients (%) Without Events (Censored)	6 (46.2%)	8 (57.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.5 (0.3, NE)	4.6 (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.047 (0.335, 3.271)
p-value			0.9468
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	113 (62.4%)	79 (44.9%)	
Patients (%) Without Events (Censored)	68 (37.6%)	97 (55.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.9, 2.2)	5.8 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.575 (1.181, 2.100)
p-value			0.0018

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9901
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.6547
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	17 (9.4%)	3 (1.7%)	
Patients (%) Without Events (Censored)	164 (90.6%)	173 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.479 (1.604, 18.711)
p-value			0.0023

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9909
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2770
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	10 (5.5%)	10 (5.7%)	
Patients (%) Without Events (Censored)	171 (94.5%)	166 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.945 (0.393, 2.271)
p-value			0.8984

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.9891
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3173
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	18 (9.9%)	7 (4.0%)	
Patients (%) Without Events (Censored)	163 (90.1%)	169 (96.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.124 (0.881, 5.117)
p-value			0.0861

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.3019
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	2 (14.3%)	
Patients (%) Without Events (Censored)	12 (92.3%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.5, NE)	4.6 (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0368
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	5 (2.8%)	5 (2.8%)	
Patients (%) Without Events (Censored)	176 (97.2%)	171 (97.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.818 (0.235, 2.841)
p-value			0.7509

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9034
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	6 (46.2%)	4 (28.6%)	
Patients (%) Without Events (Censored)	7 (53.8%)	10 (71.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.695 (0.478, 6.013)
p-value			0.4124
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	101 (55.8%)	72 (40.9%)	
Patients (%) Without Events (Censored)	80 (44.2%)	104 (59.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (1.0, 4.6)	8.3 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.492 (1.102, 2.020)
p-value			0.0092

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.4747
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	109 (61.6%)	78 (45.6%)	
Patients (%) Without Events (Censored)	68 (38.4%)	93 (54.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 1.7)	4.4 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.524 (1.139, 2.039)
p-value			0.0043
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	16 (66.7%)	8 (34.8%)	
Patients (%) Without Events (Censored)	8 (33.3%)	15 (65.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (1.0, 6.5)	NE (0.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.069 (0.885, 4.839)
p-value			0.0895

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.5787
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	15 (8.5%)	2 (1.2%)	
Patients (%) Without Events (Censored)	162 (91.5%)	169 (98.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.182 (1.640, 31.441)
p-value			0.0022
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	4 (16.7%)	1 (4.3%)	
Patients (%) Without Events (Censored)	20 (83.3%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.844 (0.316, 25.570)
p-value			0.3294

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.9886
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	11 (6.2%)	11 (6.4%)	
Patients (%) Without Events (Censored)	166 (93.8%)	160 (93.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.934 (0.405, 2.154)
p-value			0.8715
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	1 (4.2%)	0	
Patients (%) Without Events (Censored)	23 (95.8%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3276

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.7318
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	17 (9.6%)	7 (4.1%)	
Patients (%) Without Events (Censored)	160 (90.4%)	164 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.017 (0.830, 4.904)
p-value			0.1143
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	4 (16.7%)	1 (4.3%)	
Patients (%) Without Events (Censored)	20 (83.3%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.802 (0.311, 25.244)
p-value			0.3374

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neuropathy+			
Interaction p-value			0.9590
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	5 (2.8%)	6 (3.5%)	
Patients (%) Without Events (Censored)	172 (97.2%)	165 (96.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.652 (0.198, 2.153)
p-value			0.4799
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	1 (4.2%)	1 (4.3%)	
Patients (%) Without Events (Censored)	23 (95.8%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.799 (0.049, 12.926)
p-value			0.8744

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.9004
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	100 (56.5%)	70 (40.9%)	
Patients (%) Without Events (Censored)	77 (43.5%)	101 (59.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.9, 3.8)	8.3 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.513 (1.114, 2.054)
p-value			0.0075
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	11 (45.8%)	7 (30.4%)	
Patients (%) Without Events (Censored)	13 (54.2%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.640 (0.635, 4.235)
p-value			0.3126

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.5812
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	74 (60.7%)	53 (41.1%)	
Patients (%) Without Events (Censored)	48 (39.3%)	76 (58.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.8, 3.7)	5.8 (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.673 (1.175, 2.382)
p-value			0.0038
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	51 (64.6%)	33 (50.8%)	
Patients (%) Without Events (Censored)	28 (35.4%)	32 (49.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, 2.5)	3.8 (1.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.413 (0.911, 2.191)
p-value			0.1218

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Diarrhea			
Interaction p-value			0.9892
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	11 (9.0%)	3 (2.3%)	
Patients (%) Without Events (Censored)	111 (91.0%)	126 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.593 (0.999, 12.925)
p-value			0.0365
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	8 (10.1%)	0	
Patients (%) Without Events (Censored)	71 (89.9%)	65 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0097

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Febrile neutropenia			
Interaction p-value			0.6265
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	7 (5.7%)	8 (6.2%)	
Patients (%) Without Events (Censored)	115 (94.3%)	121 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.881 (0.319, 2.429)
p-value			0.8060
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	5 (6.3%)	3 (4.6%)	
Patients (%) Without Events (Censored)	74 (93.7%)	62 (95.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.363 (0.326, 5.705)
p-value			0.6708

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.4415
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	12 (9.8%)	6 (4.7%)	
Patients (%) Without Events (Censored)	110 (90.2%)	123 (95.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.811 (0.674, 4.867)
p-value			0.2332
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	9 (11.4%)	2 (3.1%)	
Patients (%) Without Events (Censored)	70 (88.6%)	63 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.207 (0.688, 14.952)
p-value			0.1172

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.6862
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	64 (52.5%)	47 (36.4%)	
Patients (%) Without Events (Censored)	58 (47.5%)	82 (63.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.0, NE)	NE (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.581 (1.084, 2.304)
p-value			0.0164
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	47 (59.5%)	30 (46.2%)	
Patients (%) Without Events (Censored)	32 (40.5%)	35 (53.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.7, 4.8)	8.3 (1.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.392 (0.880, 2.201)
p-value			0.1584

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Overall			
Interaction p-value			0.0711
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	42 (61.8%)	39 (54.2%)	
Patients (%) Without Events (Censored)	26 (38.2%)	33 (45.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.6, 4.6)	2.4 (0.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.263 (0.817, 1.954)
p-value			0.3050
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	42 (59.2%)	29 (39.2%)	
Patients (%) Without Events (Censored)	29 (40.8%)	45 (60.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (0.9, 6.9)	8.3 (3.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.434 (0.889, 2.313)
p-value			0.1364
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	27 (67.5%)	10 (38.5%)	
Patients (%) Without Events (Censored)	13 (32.5%)	16 (61.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 2.2)	9.6 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.690 (1.293, 5.595)
p-value			0.0060

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Infections			
Interaction p-value			0.7621
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	5 (7.4%)	4 (5.6%)	
Patients (%) Without Events (Censored)	63 (92.6%)	68 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.306 (0.350, 4.873)
p-value			0.6915
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	8 (11.3%)	2 (2.7%)	
Patients (%) Without Events (Censored)	63 (88.7%)	72 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.310 (0.696, 15.747)
p-value			0.1115
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	6 (15.0%)	2 (7.7%)	
Patients (%) Without Events (Censored)	34 (85.0%)	24 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.655 (0.329, 8.336)
p-value			0.5371

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Neutropenia+			
Interaction p-value			0.1471
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	38 (55.9%)	35 (48.6%)	
Patients (%) Without Events (Censored)	30 (44.1%)	37 (51.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (0.7, 4.8)	2.8 (1.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.250 (0.790, 1.980)
p-value			0.3536
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	36 (50.7%)	26 (35.1%)	
Patients (%) Without Events (Censored)	35 (49.3%)	48 (64.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.0 (1.0, NE)	8.3 (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.398 (0.842, 2.321)
p-value			0.1919
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.4.6: Time to the First Grade 3 or Higher TEAE of Special Interest by Subgroup
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	24 (60.0%)	9 (34.6%)	
Patients (%) Without Events (Censored)	16 (40.0%)	17 (65.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.5, NE)	9.6 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.335 (1.083, 5.034)
p-value			0.0266

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.
The subgroup is kept if the number of total patients in of all categories over total (SG+TPC) is no less than 10.
The subgroup is kept if at least one category has no less than 10 patients with events in total (SG and TPC).
The analysis is based on Interim 2 data cut at 7/1/2022.

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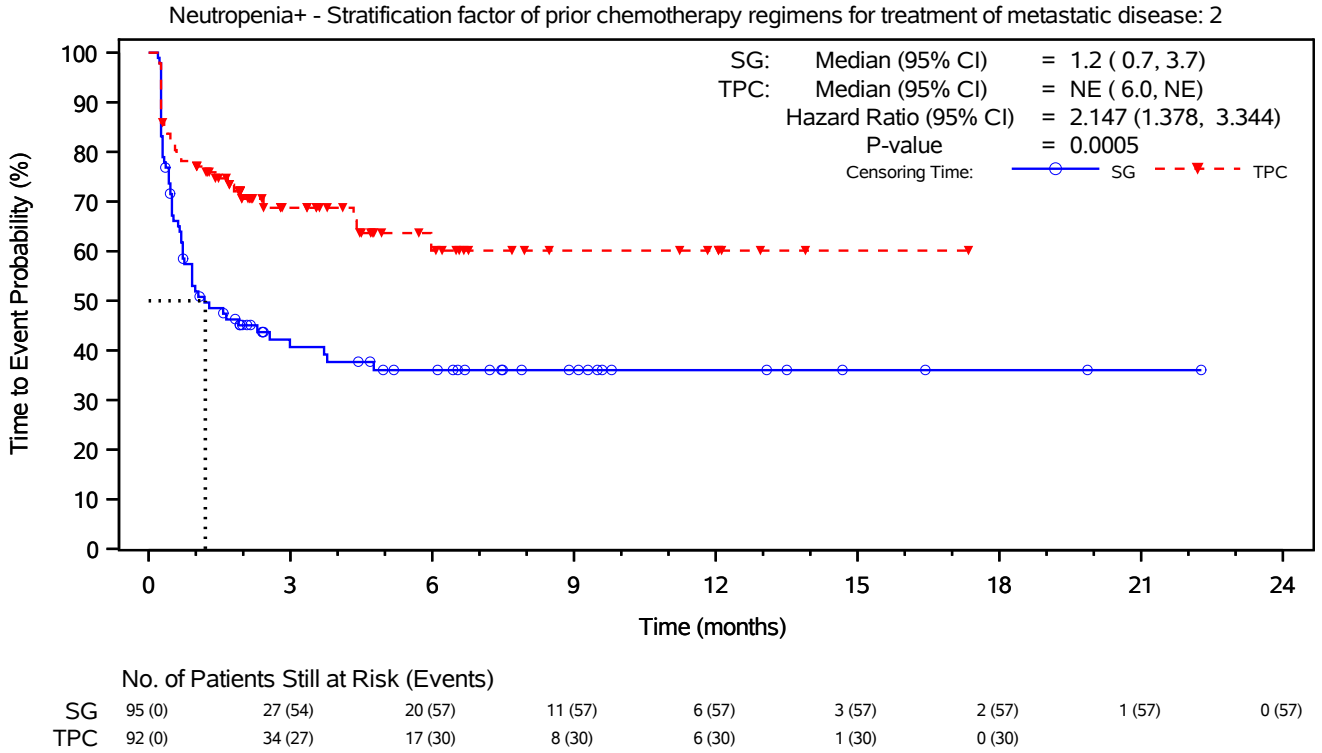
Figure 15.11.4.6.1: KM Plot for Time to the First >=Grade 3 TEAE of Special Interest by Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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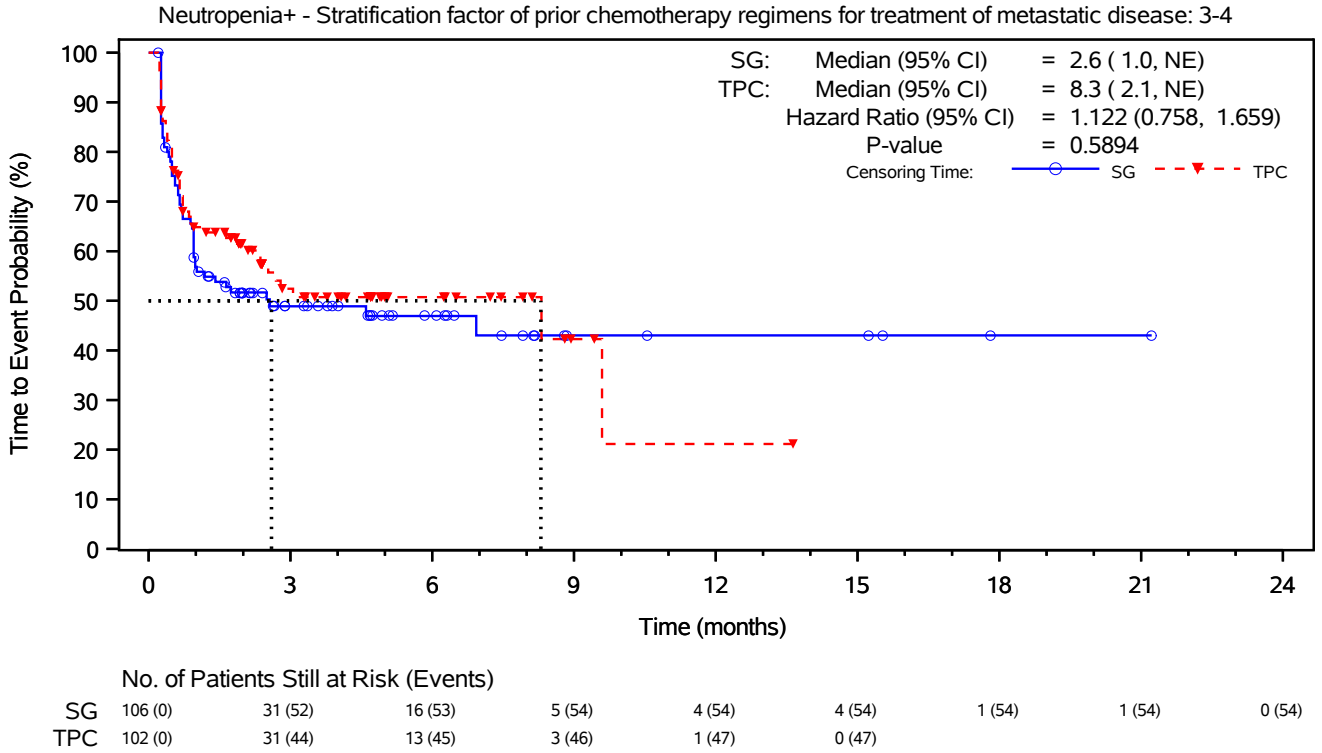
Figure 15.11.4.6.1: KM Plot for Time to the First >=Grade 3 TEAE of Special Interest by Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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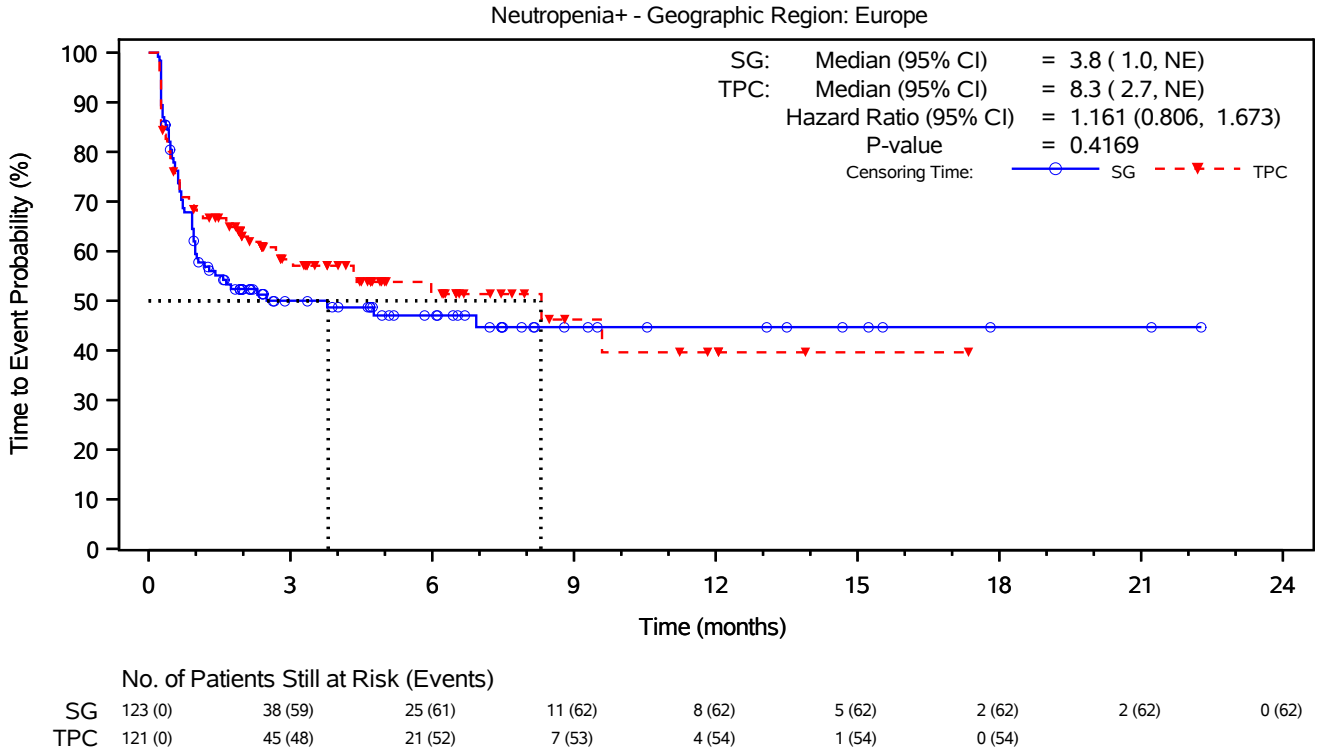
Figure 15.11.4.6.2: KM Plot for Time to the First >=Grade 3 TEAE of Special Interest by Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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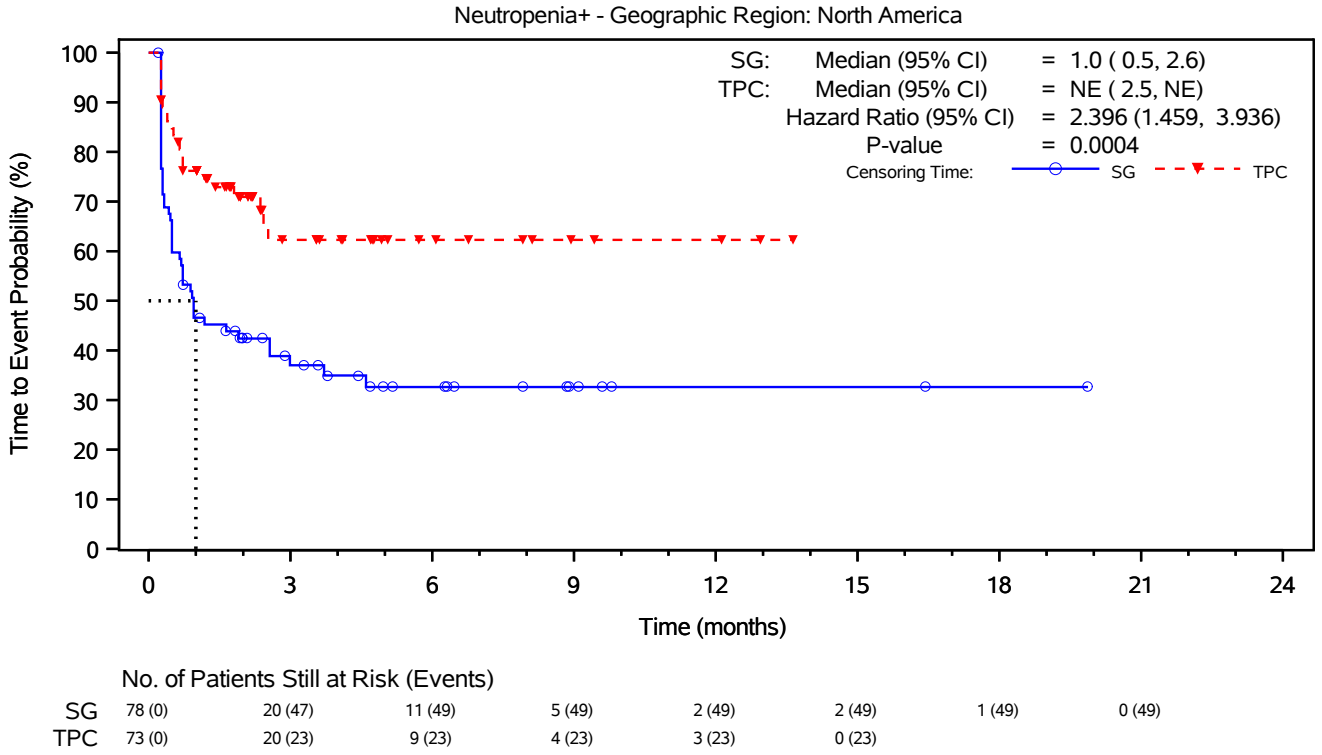
Figure 15.11.4.6.2: KM Plot for Time to the First >=Grade 3 TEAE of Special Interest by Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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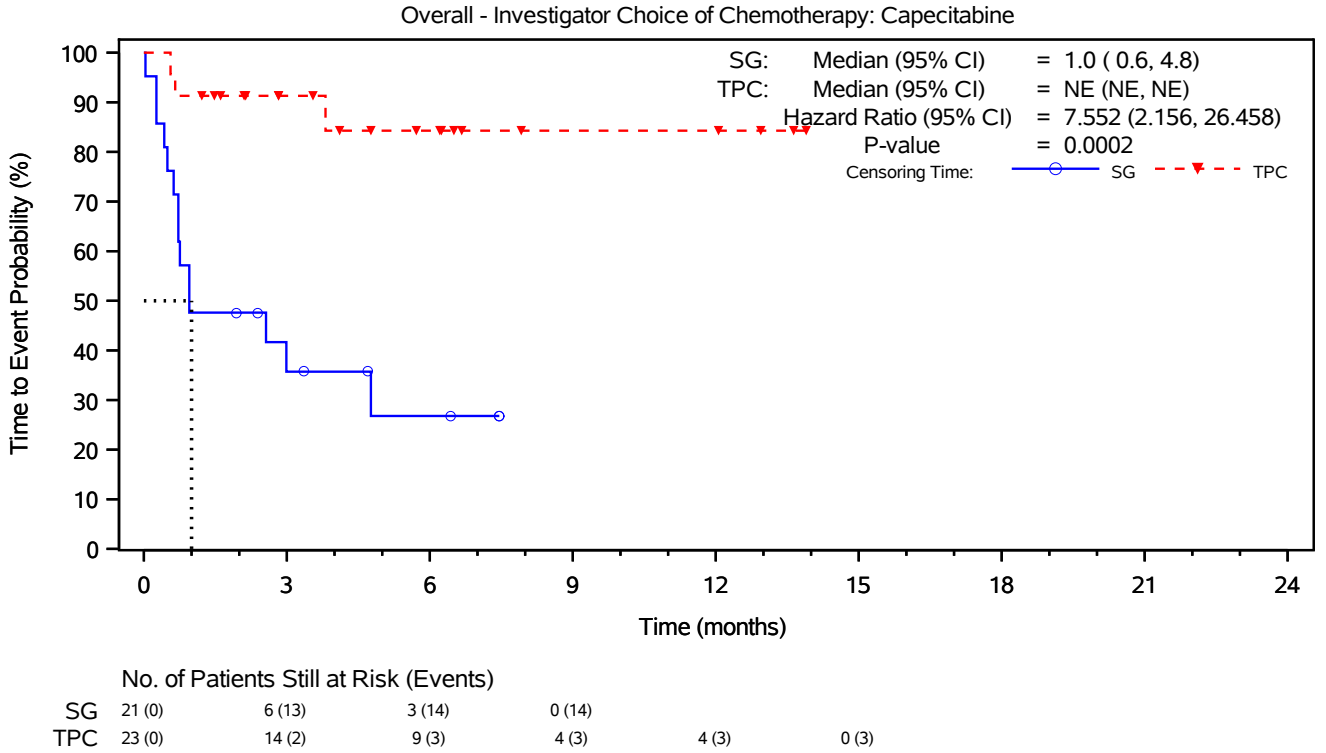
Figure 15.11.4.6.3: KM Plot for Time to the First >=Grade 3 TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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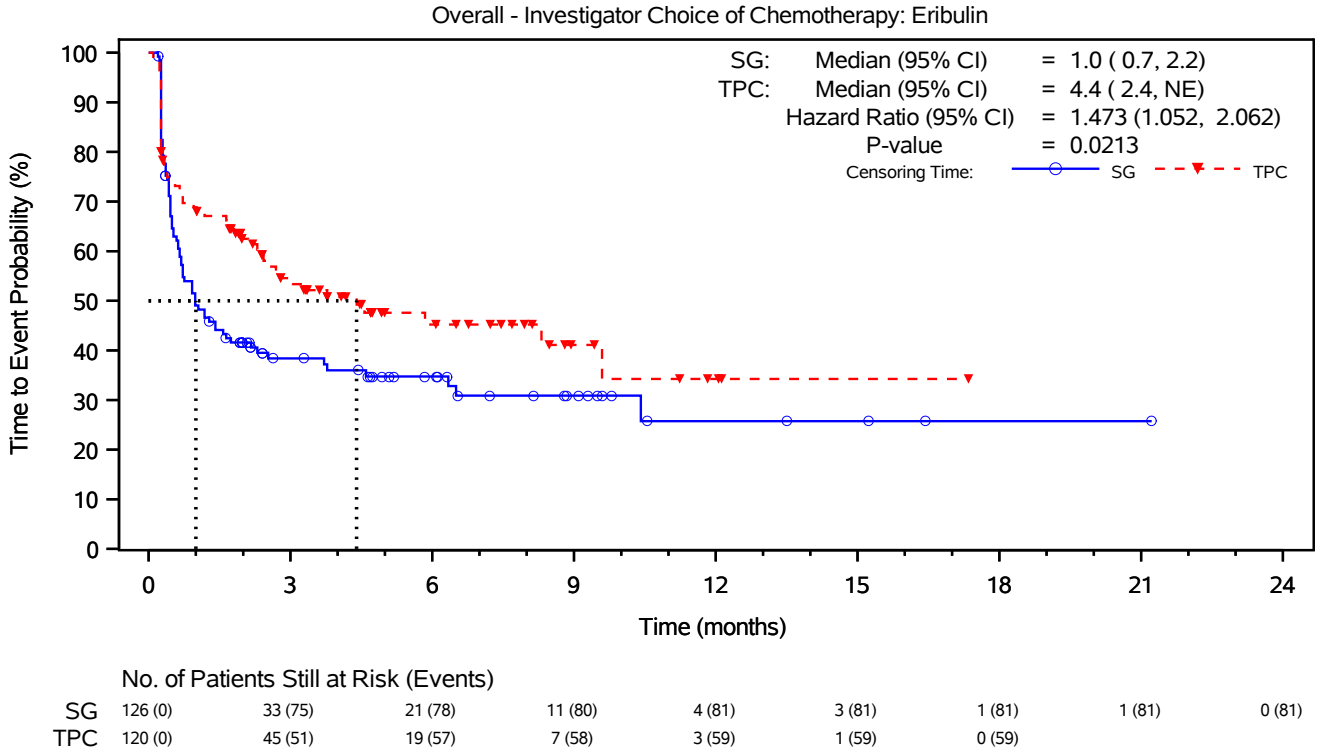
Figure 15.11.4.6.3: KM Plot for Time to the First >=Grade 3 TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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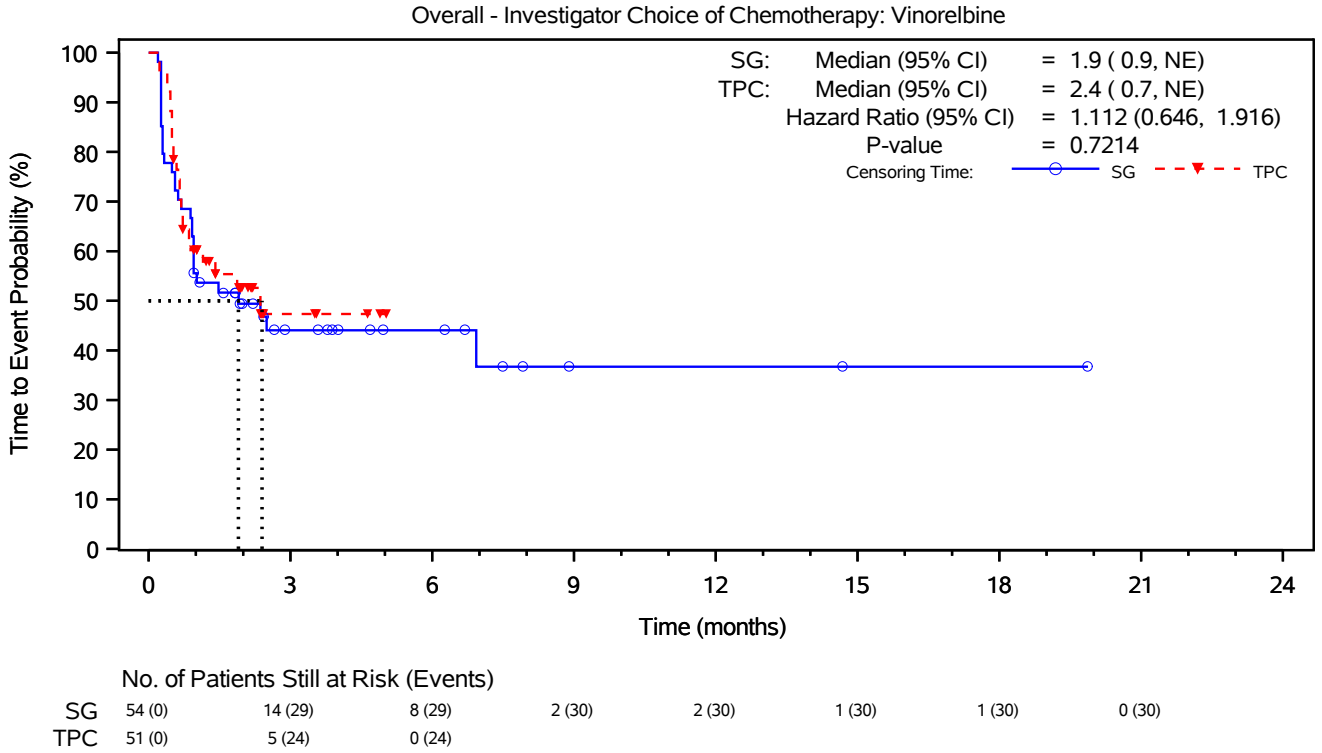
Figure 15.11.4.6.3: KM Plot for Time to the First >=Grade 3 TEAE of Special Interest by Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.2874
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	79 (83.2%)	52 (56.5%)	
Patients (%) Without Events (Censored)	16 (16.8%)	40 (43.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	2.1 (1.0, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.899 (1.334, 2.704)
p-value			0.0003
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	86 (81.1%)	66 (64.7%)	
Patients (%) Without Events (Censored)	20 (18.9%)	36 (35.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 0.7)	0.8 (0.7, 2.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.489 (1.076, 2.061)
p-value			0.0178

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.6571
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	25 (26.3%)	17 (18.5%)	
Patients (%) Without Events (Censored)	70 (73.7%)	75 (81.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.324 (0.713, 2.456)
p-value			0.3726
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	45 (42.5%)	28 (27.5%)	
Patients (%) Without Events (Censored)	61 (57.5%)	74 (72.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.6 (3.9, NE)	NE (7.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.589 (0.991, 2.549)
p-value			0.0528

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.0599
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	71 (74.7%)	42 (45.7%)	
Patients (%) Without Events (Censored)	24 (25.3%)	50 (54.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.9)	4.5 (2.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.020 (1.376, 2.964)
p-value			0.0002
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	71 (67.0%)	59 (57.8%)	
Patients (%) Without Events (Censored)	35 (33.0%)	43 (42.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 1.4)	1.9 (0.7, 4.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.254 (0.886, 1.773)
p-value			0.2092

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.0230
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	1 (1.1%)	11 (12.0%)	
Patients (%) Without Events (Censored)	94 (98.9%)	81 (88.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.072 (0.009, 0.562)
p-value			0.0010
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	11 (10.4%)	10 (9.8%)	
Patients (%) Without Events (Censored)	95 (89.6%)	92 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.991 (0.420, 2.339)
p-value			0.9841

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9759
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	90 (94.7%)	68 (73.9%)	
Patients (%) Without Events (Censored)	5 (5.3%)	24 (26.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.3)	0.8 (0.3, 1.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.996 (1.444, 2.757)
p-value			<0.0001
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	96 (90.6%)	70 (68.6%)	
Patients (%) Without Events (Censored)	10 (9.4%)	32 (31.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.5, 1.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.891 (1.382, 2.589)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.8643
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	60 (63.2%)	25 (27.2%)	
Patients (%) Without Events (Censored)	35 (36.8%)	67 (72.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (0.9, 3.4)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.915 (1.827, 4.652)
p-value			<0.0001
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	60 (56.6%)	24 (23.5%)	
Patients (%) Without Events (Censored)	46 (43.4%)	78 (76.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (1.0, 6.0)	NE (5.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.182 (1.977, 5.123)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.2748
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	62 (65.3%)	29 (31.5%)	
Patients (%) Without Events (Censored)	33 (34.7%)	63 (68.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.3, 1.7)	NE (6.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.613 (1.678, 4.069)
p-value			<0.0001
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	58 (54.7%)	35 (34.3%)	
Patients (%) Without Events (Censored)	48 (45.3%)	67 (65.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.7, NE)	NE (3.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.808 (1.186, 2.757)
p-value			0.0052

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.0865
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	26 (27.4%)	9 (9.8%)	
Patients (%) Without Events (Censored)	69 (72.6%)	83 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.750 (1.288, 5.872)
p-value			0.0064
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	24 (22.6%)	18 (17.6%)	
Patients (%) Without Events (Censored)	82 (77.4%)	84 (82.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.195 (0.645, 2.213)
p-value			0.5677

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.1383
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	2 (2.1%)	9 (9.8%)	
Patients (%) Without Events (Censored)	93 (97.9%)	83 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.185 (0.040, 0.860)
p-value			0.0159
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	4 (3.8%)	4 (3.9%)	
Patients (%) Without Events (Censored)	102 (96.2%)	98 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.793 (0.195, 3.235)
p-value			0.7465

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.9761
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	12 (12.6%)	4 (4.3%)	
Patients (%) Without Events (Censored)	83 (87.4%)	88 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.691 (0.864, 8.382)
p-value			0.0753
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	12 (11.3%)	4 (3.9%)	
Patients (%) Without Events (Censored)	94 (88.7%)	98 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.721 (0.876, 8.451)
p-value			0.0713

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.8020
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	6 (6.3%)	10 (10.9%)	
Patients (%) Without Events (Censored)	89 (93.7%)	82 (89.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.412 (0.147, 1.154)
p-value			0.0820
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	5 (4.7%)	7 (6.9%)	
Patients (%) Without Events (Censored)	101 (95.3%)	95 (93.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.620 (0.196, 1.958)
p-value			0.4124

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.2241
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	37 (38.9%)	35 (38.0%)	
Patients (%) Without Events (Censored)	58 (61.1%)	57 (62.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.9 (5.6, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.891 (0.560, 1.418)
p-value			0.6300
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	37 (34.9%)	49 (48.0%)	
Patients (%) Without Events (Censored)	69 (65.1%)	53 (52.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.3, NE)	3.2 (2.1, 5.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.613 (0.399, 0.940)
p-value			0.0240

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.9761
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	4 (4.2%)	8 (8.7%)	
Patients (%) Without Events (Censored)	91 (95.8%)	84 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.404 (0.121, 1.344)
p-value			0.1265
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	5 (4.7%)	10 (9.8%)	
Patients (%) Without Events (Censored)	101 (95.3%)	92 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.353 (0.119, 1.048)
p-value			0.0508

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.7938
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	4 (4.2%)	7 (7.6%)	
Patients (%) Without Events (Censored)	91 (95.8%)	85 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.374 (0.096, 1.447)
p-value			0.1378
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	3 (2.8%)	7 (6.9%)	
Patients (%) Without Events (Censored)	103 (97.2%)	95 (93.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.333 (0.086, 1.295)
p-value			0.0963

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.7327
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	42 (44.2%)	28 (30.4%)	
Patients (%) Without Events (Censored)	53 (55.8%)	64 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.9 (3.4, NE)	11.0 (7.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.512 (0.937, 2.440)
p-value			0.0878
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	44 (41.5%)	31 (30.4%)	
Patients (%) Without Events (Censored)	62 (58.5%)	71 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.7 (2.7, NE)	10.1 (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.367 (0.860, 2.173)
p-value			0.1859

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.6937
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	6 (6.3%)	1 (1.1%)	
Patients (%) Without Events (Censored)	89 (93.7%)	91 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.270 (0.634, 43.836)
p-value			0.0854
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	11 (10.4%)	3 (2.9%)	
Patients (%) Without Events (Censored)	95 (89.6%)	99 (97.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.189 (0.878, 11.589)
p-value			0.0627

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.4516
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	58 (61.1%)	41 (44.6%)	
Patients (%) Without Events (Censored)	37 (38.9%)	51 (55.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 2.5)	5.5 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.665 (1.115, 2.487)
p-value			0.0122
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	62 (58.5%)	38 (37.3%)	
Patients (%) Without Events (Censored)	44 (41.5%)	64 (62.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.7, 2.8)	8.7 (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.001 (1.335, 3.000)
p-value			0.0006

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.9790
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	50 (52.6%)	23 (25.0%)	
Patients (%) Without Events (Censored)	45 (47.4%)	69 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.634 (1.605, 4.321)
p-value			<0.0001
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	48 (45.3%)	22 (21.6%)	
Patients (%) Without Events (Censored)	58 (54.7%)	80 (78.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.553 (1.540, 4.232)
p-value			0.0002

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.9918
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	4 (4.2%)	8 (8.7%)	
Patients (%) Without Events (Censored)	91 (95.8%)	84 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.402 (0.120, 1.344)
p-value			0.1259
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	0	6 (5.9%)	
Patients (%) Without Events (Censored)	106 (100.0%)	96 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0059

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.1: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.6623
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	9 (9.5%)	1 (1.1%)	
Patients (%) Without Events (Censored)	86 (90.5%)	91 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			8.654 (1.096, 68.315)
p-value			0.0135
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	15 (14.2%)	3 (2.9%)	
Patients (%) Without Events (Censored)	91 (85.8%)	99 (97.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.651 (1.342, 16.116)
p-value			0.0077

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.9746
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	157 (81.8%)	113 (60.8%)	
Patients (%) Without Events (Censored)	35 (18.2%)	73 (39.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.7)	1.7 (0.7, 2.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.677 (1.314, 2.140)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	8 (88.9%)	5 (62.5%)	
Patients (%) Without Events (Censored)	1 (11.1%)	3 (37.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, NE)	1.3 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.652 (0.538, 5.068)
p-value			0.3744

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.9124
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	66 (34.4%)	43 (23.1%)	
Patients (%) Without Events (Censored)	126 (65.6%)	143 (76.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.9, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.466 (0.998, 2.154)
p-value			0.0511
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	4 (44.4%)	2 (25.0%)	
Patients (%) Without Events (Censored)	5 (55.6%)	6 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.3 (1.2, NE)	NE (0.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.517 (0.276, 8.330)
p-value			0.6294

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.6422
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	136 (70.8%)	96 (51.6%)	
Patients (%) Without Events (Censored)	56 (29.2%)	90 (48.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	4.1 (1.6, 6.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.587 (1.221, 2.063)
p-value			0.0005
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	6 (66.7%)	5 (62.5%)	
Patients (%) Without Events (Censored)	3 (33.3%)	3 (37.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, NE)	1.3 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.288 (0.392, 4.229)
p-value			0.6818

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.9997
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	12 (6.3%)	21 (11.3%)	
Patients (%) Without Events (Censored)	180 (93.8%)	165 (88.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.490 (0.241, 1.000)
p-value			0.0452
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9523
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	178 (92.7%)	132 (71.0%)	
Patients (%) Without Events (Censored)	14 (7.3%)	54 (29.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.5, 1.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.949 (1.549, 2.453)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	8 (88.9%)	6 (75.0%)	
Patients (%) Without Events (Censored)	1 (11.1%)	2 (25.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.0, 0.8)	0.9 (0.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.165 (0.728, 6.439)
p-value			0.1315

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
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Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.8063
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	115 (59.9%)	47 (25.3%)	
Patients (%) Without Events (Censored)	77 (40.1%)	139 (74.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.3, 3.3)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.077 (2.190, 4.324)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	5 (55.6%)	2 (25.0%)	
Patients (%) Without Events (Censored)	4 (44.4%)	6 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.8 (0.2, NE)	NE (0.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.359 (0.444, 12.540)
p-value			0.3007

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
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The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.0995
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	113 (58.9%)	63 (33.9%)	
Patients (%) Without Events (Censored)	79 (41.1%)	123 (66.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.8, 3.5)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.050 (1.505, 2.793)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	7 (77.8%)	1 (12.5%)	
Patients (%) Without Events (Censored)	2 (22.2%)	7 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.0, NE)	NE (1.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			12.357 (1.473, 103.635)
p-value			0.0041

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The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.5864
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	49 (25.5%)	26 (14.0%)	
Patients (%) Without Events (Censored)	143 (74.5%)	160 (86.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.742 (1.081, 2.808)
p-value			0.0208
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	1 (12.5%)	
Patients (%) Without Events (Censored)	8 (88.9%)	7 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.5, NE)	NE (1.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.504 (0.028, 9.015)
p-value			0.6363

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
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Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.9899
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	6 (3.1%)	12 (6.5%)	
Patients (%) Without Events (Censored)	186 (96.9%)	174 (93.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.416 (0.155, 1.115)
p-value			0.0723
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	1 (12.5%)	
Patients (%) Without Events (Censored)	9 (100.0%)	7 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (1.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2888

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.9884
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	22 (11.5%)	8 (4.3%)	
Patients (%) Without Events (Censored)	170 (88.5%)	178 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.472 (1.097, 5.574)
p-value			0.0240
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	2 (22.2%)	0	
Patients (%) Without Events (Censored)	7 (77.8%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.6, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2060

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.7430
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	10 (5.2%)	15 (8.1%)	
Patients (%) Without Events (Censored)	182 (94.8%)	171 (91.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.500 (0.222, 1.126)
p-value			0.0880
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	2 (25.0%)	
Patients (%) Without Events (Censored)	8 (88.9%)	6 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.5, NE)	NE (0.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.289 (0.024, 3.456)
p-value			0.3017

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.9697
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	71 (37.0%)	84 (45.2%)	
Patients (%) Without Events (Censored)	121 (63.0%)	102 (54.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (9.3, NE)	3.6 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.697 (0.507, 0.957)
p-value			0.0251
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	3 (33.3%)	0	
Patients (%) Without Events (Censored)	6 (66.7%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2168

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.9886
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	7 (3.6%)	18 (9.7%)	
Patients (%) Without Events (Censored)	185 (96.4%)	168 (90.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.303 (0.126, 0.729)
p-value			0.0048
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	2 (22.2%)	0	
Patients (%) Without Events (Censored)	7 (77.8%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3354

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.9997
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	7 (3.6%)	14 (7.5%)	
Patients (%) Without Events (Censored)	185 (96.4%)	172 (92.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.354 (0.136, 0.924)
p-value			0.0268
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.6593
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	83 (43.2%)	58 (31.2%)	
Patients (%) Without Events (Censored)	109 (56.8%)	128 (68.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.5 (3.8, NE)	10.1 (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.425 (1.018, 1.995)
p-value			0.0382
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	3 (33.3%)	1 (12.5%)	
Patients (%) Without Events (Censored)	6 (66.7%)	7 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.1, NE)	NE (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.837 (0.189, 17.892)
p-value			0.5949

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.9996
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	17 (8.9%)	4 (2.2%)	
Patients (%) Without Events (Censored)	175 (91.1%)	182 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.776 (1.264, 11.277)
p-value			0.0106
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.7962
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	113 (58.9%)	75 (40.3%)	
Patients (%) Without Events (Censored)	79 (41.1%)	111 (59.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.3)	5.7 (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.804 (1.346, 2.417)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	7 (77.8%)	4 (50.0%)	
Patients (%) Without Events (Censored)	2 (22.2%)	4 (50.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.2, NE)	3.0 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.732 (0.480, 6.247)
p-value			0.3958

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.6583
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	92 (47.9%)	43 (23.1%)	
Patients (%) Without Events (Censored)	100 (52.1%)	143 (76.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.2 (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.543 (1.769, 3.655)
p-value			<0.0001
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	6 (66.7%)	2 (25.0%)	
Patients (%) Without Events (Censored)	3 (33.3%)	6 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.3, NE)	NE (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.328 (0.663, 16.716)
p-value			0.1252

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.9910
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	4 (2.1%)	13 (7.0%)	
Patients (%) Without Events (Censored)	188 (97.9%)	173 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.227 (0.073, 0.712)
p-value			0.0058
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	1 (12.5%)	
Patients (%) Without Events (Censored)	9 (100.0%)	7 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (3.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1266

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.2: Time to the First Frequent TEAE by SOC, PT and Subgroup: Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9899
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	22 (11.5%)	4 (2.2%)	
Patients (%) Without Events (Censored)	170 (88.5%)	182 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.260 (1.811, 15.277)
p-value			0.0006
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	2 (22.2%)	0	
Patients (%) Without Events (Censored)	7 (77.8%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2416

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.3221
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	149 (82.8%)	103 (60.2%)	
Patients (%) Without Events (Censored)	31 (17.2%)	68 (39.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 0.7)	1.7 (0.8, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.741 (1.352, 2.242)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	16 (76.2%)	15 (65.2%)	
Patients (%) Without Events (Censored)	5 (23.8%)	8 (34.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.3, 1.4)	0.7 (0.3, 2.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.137 (0.551, 2.348)
p-value			0.7416

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.1080
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	61 (33.9%)	42 (24.6%)	
Patients (%) Without Events (Censored)	119 (66.1%)	129 (75.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.9, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.325 (0.894, 1.965)
p-value			0.1625
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	9 (42.9%)	3 (13.0%)	
Patients (%) Without Events (Censored)	12 (57.1%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.0 (1.0, NE)	NE (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.598 (0.968, 13.365)
p-value			0.0412

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.2803
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	130 (72.2%)	88 (51.5%)	
Patients (%) Without Events (Censored)	50 (27.8%)	83 (48.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	4.1 (1.6, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.639 (1.250, 2.150)
p-value			0.0003
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	12 (57.1%)	13 (56.5%)	
Patients (%) Without Events (Censored)	9 (42.9%)	10 (43.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.6, NE)	1.9 (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.099 (0.496, 2.437)
p-value			0.8271

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.7595
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	11 (6.1%)	18 (10.5%)	
Patients (%) Without Events (Censored)	169 (93.9%)	153 (89.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.511 (0.241, 1.086)
p-value			0.0754
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	3 (13.0%)	
Patients (%) Without Events (Censored)	20 (95.2%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.299 (0.031, 2.906)
p-value			0.2702

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.2835
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	168 (93.3%)	120 (70.2%)	
Patients (%) Without Events (Censored)	12 (6.7%)	51 (29.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.6, 1.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.042 (1.607, 2.595)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	18 (85.7%)	18 (78.3%)	
Patients (%) Without Events (Censored)	3 (14.3%)	5 (21.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.5)	0.7 (0.1, 1.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.386 (0.715, 2.688)
p-value			0.3312

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9429
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	108 (60.0%)	44 (25.7%)	
Patients (%) Without Events (Censored)	72 (40.0%)	127 (74.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.2, 3.4)	NE (8.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.053 (2.148, 4.338)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	12 (57.1%)	5 (21.7%)	
Patients (%) Without Events (Censored)	9 (42.9%)	18 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.7 (0.5, NE)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.150 (1.100, 9.024)
p-value			0.0245

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.3684
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	107 (59.4%)	53 (31.0%)	
Patients (%) Without Events (Censored)	73 (40.6%)	118 (69.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.8, 3.5)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.313 (1.663, 3.218)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	13 (61.9%)	11 (47.8%)	
Patients (%) Without Events (Censored)	8 (38.1%)	12 (52.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.1, NE)	7.6 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.559 (0.694, 3.504)
p-value			0.2802

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.9437
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	47 (26.1%)	25 (14.6%)	
Patients (%) Without Events (Censored)	133 (73.9%)	146 (85.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.695 (1.041, 2.757)
p-value			0.0317
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	2 (8.7%)	
Patients (%) Without Events (Censored)	18 (85.7%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.667 (0.278, 9.975)
p-value			0.5716

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.9997
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	6 (3.3%)	13 (7.6%)	
Patients (%) Without Events (Censored)	174 (96.7%)	158 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.371 (0.140, 0.984)
p-value			0.0382
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	21 (100.0%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.9879
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	21 (11.7%)	8 (4.7%)	
Patients (%) Without Events (Censored)	159 (88.3%)	163 (95.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.374 (1.051, 5.364)
p-value			0.0320
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	0	
Patients (%) Without Events (Censored)	18 (85.7%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.1 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1196

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.4238
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	9 (5.0%)	15 (8.8%)	
Patients (%) Without Events (Censored)	171 (95.0%)	156 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.432 (0.187, 1.000)
p-value			0.0440
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	2 (8.7%)	
Patients (%) Without Events (Censored)	19 (90.5%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.909 (0.123, 6.747)
p-value			0.9261

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.3813
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	67 (37.2%)	77 (45.0%)	
Patients (%) Without Events (Censored)	113 (62.8%)	94 (55.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.1, NE)	3.7 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.686 (0.493, 0.954)
p-value			0.0243
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	7 (33.3%)	7 (30.4%)	
Patients (%) Without Events (Censored)	14 (66.7%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (1.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.210 (0.423, 3.455)
p-value			0.7326

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.9895
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	9 (5.0%)	16 (9.4%)	
Patients (%) Without Events (Censored)	171 (95.0%)	155 (90.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.422 (0.186, 0.960)
p-value			0.0339
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	0	2 (8.7%)	
Patients (%) Without Events (Censored)	21 (100.0%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1915

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.9906
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	7 (3.9%)	13 (7.6%)	
Patients (%) Without Events (Censored)	173 (96.1%)	158 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.373 (0.142, 0.985)
p-value			0.0384
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	0	1 (4.3%)	
Patients (%) Without Events (Censored)	21 (100.0%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3642

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.8951
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	78 (43.3%)	52 (30.4%)	
Patients (%) Without Events (Censored)	102 (56.7%)	119 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.9 (3.9, NE)	NE (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.442 (1.014, 2.049)
p-value			0.0407
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	8 (38.1%)	7 (30.4%)	
Patients (%) Without Events (Censored)	13 (61.9%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.7 (2.5, NE)	8.3 (2.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.932 (0.629, 5.930)
p-value			0.2452

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.9892
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	17 (9.4%)	3 (1.8%)	
Patients (%) Without Events (Censored)	163 (90.6%)	168 (98.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.005 (1.462, 17.141)
p-value			0.0044
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	0	1 (4.3%)	
Patients (%) Without Events (Censored)	21 (100.0%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (8.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3173

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.4308
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	111 (61.7%)	74 (43.3%)	
Patients (%) Without Events (Censored)	69 (38.3%)	97 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 2.1)	5.5 (3.1, 8.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.752 (1.304, 2.354)
p-value			0.0002
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	9 (42.9%)	5 (21.7%)	
Patients (%) Without Events (Censored)	12 (57.1%)	18 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.5, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.401 (0.798, 7.221)
p-value			0.1074

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.1324
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	90 (50.0%)	44 (25.7%)	
Patients (%) Without Events (Censored)	90 (50.0%)	127 (74.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (0.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.373 (1.653, 3.405)
p-value			<0.0001
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	8 (38.1%)	1 (4.3%)	
Patients (%) Without Events (Censored)	13 (61.9%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			10.704 (1.333, 85.942)
p-value			0.0055

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.5726
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	3 (1.7%)	12 (7.0%)	
Patients (%) Without Events (Censored)	177 (98.3%)	159 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.199 (0.056, 0.707)
p-value			0.0056
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	2 (8.7%)	
Patients (%) Without Events (Censored)	20 (95.2%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	16.7 (NE, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1502

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.3: Time to the First Frequent TEAE by SOC, PT and Subgroup: Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9896
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	22 (12.2%)	4 (2.3%)	
Patients (%) Without Events (Censored)	158 (87.8%)	167 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.070 (1.745, 14.730)
p-value			0.0009
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	0	
Patients (%) Without Events (Censored)	19 (90.5%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1212

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.2519
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	125 (80.6%)	90 (61.2%)	
Patients (%) Without Events (Censored)	30 (19.4%)	57 (38.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 0.7)	1.6 (0.7, 2.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.541 (1.174, 2.024)
p-value			0.0018
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	40 (87.0%)	28 (59.6%)	
Patients (%) Without Events (Censored)	6 (13.0%)	19 (40.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.4, 0.8)	2.0 (0.7, 6.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.316 (1.401, 3.828)
p-value			0.0008

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.6024
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	53 (34.2%)	31 (21.1%)	
Patients (%) Without Events (Censored)	102 (65.8%)	116 (78.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.610 (1.033, 2.510)
p-value			0.0344
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	17 (37.0%)	14 (29.8%)	
Patients (%) Without Events (Censored)	29 (63.0%)	33 (70.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (4.7, NE)	13.4 (4.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.242 (0.611, 2.523)
p-value			0.5475

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.7434
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	113 (72.9%)	79 (53.7%)	
Patients (%) Without Events (Censored)	42 (27.1%)	68 (46.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.4 (0.8, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.508 (1.130, 2.012)
p-value			0.0050
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	29 (63.0%)	22 (46.8%)	
Patients (%) Without Events (Censored)	17 (37.0%)	25 (53.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 1.6)	4.4 (1.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.701 (0.974, 2.969)
p-value			0.0615

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.3123
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	9 (5.8%)	18 (12.2%)	
Patients (%) Without Events (Censored)	146 (94.2%)	129 (87.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.414 (0.185, 0.926)
p-value			0.0267
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	3 (6.5%)	3 (6.4%)	
Patients (%) Without Events (Censored)	43 (93.5%)	44 (93.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.982 (0.198, 4.878)
p-value			0.9827

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.8800
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	143 (92.3%)	101 (68.7%)	
Patients (%) Without Events (Censored)	12 (7.7%)	46 (31.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	1.0 (0.6, 1.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.981 (1.527, 2.569)
p-value			<0.0001
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	43 (93.5%)	37 (78.7%)	
Patients (%) Without Events (Censored)	3 (6.5%)	10 (21.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.3)	0.7 (0.3, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.060 (1.307, 3.247)
p-value			0.0016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.2896
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	87 (56.1%)	35 (23.8%)	
Patients (%) Without Events (Censored)	68 (43.9%)	112 (76.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (1.5, 6.0)	NE (8.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.806 (1.893, 4.161)
p-value			<0.0001
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	33 (71.7%)	14 (29.8%)	
Patients (%) Without Events (Censored)	13 (28.3%)	33 (70.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 2.7)	7.6 (4.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.187 (2.228, 7.868)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.7177
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	94 (60.6%)	50 (34.0%)	
Patients (%) Without Events (Censored)	61 (39.4%)	97 (66.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.6)	NE (6.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.115 (1.500, 2.983)
p-value			<0.0001
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	26 (56.5%)	14 (29.8%)	
Patients (%) Without Events (Censored)	20 (43.5%)	33 (70.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.3, NE)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.396 (1.245, 4.611)
p-value			0.0070

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.5452
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	40 (25.8%)	20 (13.6%)	
Patients (%) Without Events (Censored)	115 (74.2%)	127 (86.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.828 (1.067, 3.131)
p-value			0.0256
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	10 (21.7%)	7 (14.9%)	
Patients (%) Without Events (Censored)	36 (78.3%)	40 (85.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.263 (0.474, 3.365)
p-value			0.6374

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.1908
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	5 (3.2%)	6 (4.1%)	
Patients (%) Without Events (Censored)	150 (96.8%)	141 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.634 (0.191, 2.109)
p-value			0.4540
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	1 (2.2%)	7 (14.9%)	
Patients (%) Without Events (Censored)	45 (97.8%)	40 (85.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.136 (0.017, 1.109)
p-value			0.0287

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.9967
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	16 (10.3%)	5 (3.4%)	
Patients (%) Without Events (Censored)	139 (89.7%)	142 (96.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.701 (0.981, 7.437)
p-value			0.0452
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	8 (17.4%)	3 (6.4%)	
Patients (%) Without Events (Censored)	38 (82.6%)	44 (93.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.813 (0.745, 10.616)
p-value			0.1109

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.1885
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	8 (5.2%)	15 (10.2%)	
Patients (%) Without Events (Censored)	147 (94.8%)	132 (89.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.351 (0.145, 0.847)
p-value			0.0153
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	3 (6.5%)	2 (4.3%)	
Patients (%) Without Events (Censored)	43 (93.5%)	45 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.541 (0.257, 9.246)
p-value			0.6334

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.4236
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	57 (36.8%)	67 (45.6%)	
Patients (%) Without Events (Censored)	98 (63.2%)	80 (54.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.1, NE)	3.7 (2.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.678 (0.475, 0.968)
p-value			0.0310
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	17 (37.0%)	17 (36.2%)	
Patients (%) Without Events (Censored)	29 (63.0%)	30 (63.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.9 (3.1, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.912 (0.465, 1.791)
p-value			0.7972

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.1078
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	6 (3.9%)	16 (10.9%)	
Patients (%) Without Events (Censored)	149 (96.1%)	131 (89.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.273 (0.106, 0.704)
p-value			0.0041
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	3 (6.5%)	2 (4.3%)	
Patients (%) Without Events (Censored)	43 (93.5%)	45 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.430 (0.239, 8.566)
p-value			0.6922

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.6970
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	6 (3.9%)	11 (7.5%)	
Patients (%) Without Events (Censored)	149 (96.1%)	136 (92.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.364 (0.126, 1.050)
p-value			0.0515
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	1 (2.2%)	3 (6.4%)	
Patients (%) Without Events (Censored)	45 (97.8%)	44 (93.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.302 (0.031, 2.915)
p-value			0.2724

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.4981
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	69 (44.5%)	42 (28.6%)	
Patients (%) Without Events (Censored)	86 (55.5%)	105 (71.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.5 (3.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.567 (1.067, 2.301)
p-value			0.0210
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	17 (37.0%)	17 (36.2%)	
Patients (%) Without Events (Censored)	29 (63.0%)	30 (63.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.9 (3.6, NE)	8.3 (3.9, 11.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.181 (0.600, 2.325)
p-value			0.6349

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.2208
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	14 (9.0%)	2 (1.4%)	
Patients (%) Without Events (Censored)	141 (91.0%)	145 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.432 (1.461, 28.307)
p-value			0.0046
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	3 (6.5%)	2 (4.3%)	
Patients (%) Without Events (Censored)	43 (93.5%)	45 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (8.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.227 (0.198, 7.596)
p-value			0.8257

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.4806
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	94 (60.6%)	58 (39.5%)	
Patients (%) Without Events (Censored)	61 (39.4%)	89 (60.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.1)	8.2 (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.933 (1.393, 2.683)
p-value			<0.0001
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	26 (56.5%)	21 (44.7%)	
Patients (%) Without Events (Censored)	20 (43.5%)	26 (55.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (0.5, 14.3)	3.5 (1.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.457 (0.810, 2.623)
p-value			0.2022

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.1839
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	78 (50.3%)	30 (20.4%)	
Patients (%) Without Events (Censored)	77 (49.7%)	117 (79.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (0.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.020 (1.981, 4.604)
p-value			<0.0001
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	20 (43.5%)	15 (31.9%)	
Patients (%) Without Events (Censored)	26 (56.5%)	32 (68.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.7, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.639 (0.836, 3.211)
p-value			0.1433

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.5460
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	3 (1.9%)	8 (5.4%)	
Patients (%) Without Events (Censored)	152 (98.1%)	139 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.240 (0.061, 0.941)
p-value			0.0276
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	1 (2.2%)	6 (12.8%)	
Patients (%) Without Events (Censored)	45 (97.8%)	41 (87.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.158 (0.019, 1.314)
p-value			0.0502

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.4: Time to the First Frequent TEAE by SOC, PT and Subgroup: Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.1930
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	20 (12.9%)	2 (1.4%)	
Patients (%) Without Events (Censored)	135 (87.1%)	145 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			9.322 (2.177, 39.912)
p-value			0.0002
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	4 (8.7%)	2 (4.3%)	
Patients (%) Without Events (Censored)	42 (91.3%)	45 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.149 (0.393, 11.741)
p-value			0.3658

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.8860
Race: White			
Total Patients	141	132	
Patients (%) With Events	115 (81.6%)	78 (59.1%)	
Patients (%) Without Events (Censored)	26 (18.4%)	54 (40.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	1.8 (0.7, 4.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.665 (1.247, 2.223)
p-value			0.0005
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	11 (84.6%)	10 (62.5%)	
Patients (%) Without Events (Censored)	2 (15.4%)	6 (37.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, 0.7)	0.7 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.694 (0.717, 3.999)
p-value			0.2554

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.2845
Race: White			
Total Patients	141	132	
Patients (%) With Events	47 (33.3%)	27 (20.5%)	
Patients (%) Without Events (Censored)	94 (66.7%)	105 (79.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.6, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.562 (0.972, 2.511)
p-value			0.0643
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	3 (23.1%)	5 (31.3%)	
Patients (%) Without Events (Censored)	10 (76.9%)	11 (68.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.2, NE)	6.5 (4.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.719 (0.172, 3.011)
p-value			0.6563

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.9525
Race: White			
Total Patients	141	132	
Patients (%) With Events	100 (70.9%)	70 (53.0%)	
Patients (%) Without Events (Censored)	41 (29.1%)	62 (47.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.4 (0.8, 6.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.538 (1.132, 2.090)
p-value			0.0056
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	11 (84.6%)	10 (62.5%)	
Patients (%) Without Events (Censored)	2 (15.4%)	6 (37.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 3.1)	0.8 (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.581 (0.670, 3.734)
p-value			0.3131

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.9998
Race: White			
Total Patients	141	132	
Patients (%) With Events	10 (7.1%)	16 (12.1%)	
Patients (%) Without Events (Censored)	131 (92.9%)	116 (87.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.532 (0.241, 1.175)
p-value			0.1122
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.5704
Race: White			
Total Patients	141	132	
Patients (%) With Events	129 (91.5%)	90 (68.2%)	
Patients (%) Without Events (Censored)	12 (8.5%)	42 (31.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.5, 1.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.980 (1.503, 2.607)
p-value			<0.0001
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	13 (100.0%)	12 (75.0%)	
Patients (%) Without Events (Censored)	0	4 (25.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.0, 1.0)	1.2 (0.4, 3.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.428 (1.091, 5.404)
p-value			0.0287

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.4806
Race: White			
Total Patients	141	132	
Patients (%) With Events	85 (60.3%)	33 (25.0%)	
Patients (%) Without Events (Censored)	56 (39.7%)	99 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.2, 2.9)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.088 (2.062, 4.625)
p-value			<0.0001
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	7 (53.8%)	5 (31.3%)	
Patients (%) Without Events (Censored)	6 (46.2%)	11 (68.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.0 (0.1, NE)	NE (1.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.717 (0.522, 5.644)
p-value			0.3648

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.4197
Race: White			
Total Patients	141	132	
Patients (%) With Events	80 (56.7%)	40 (30.3%)	
Patients (%) Without Events (Censored)	61 (43.3%)	92 (69.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.8, 6.0)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.221 (1.517, 3.251)
p-value			<0.0001
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	10 (76.9%)	5 (31.3%)	
Patients (%) Without Events (Censored)	3 (23.1%)	11 (68.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.1, NE)	NE (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.501 (1.190, 10.298)
p-value			0.0162

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.7704
Race: White			
Total Patients	141	132	
Patients (%) With Events	40 (28.4%)	20 (15.2%)	
Patients (%) Without Events (Censored)	101 (71.6%)	112 (84.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.743 (1.014, 2.997)
p-value			0.0413
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	2 (15.4%)	2 (12.5%)	
Patients (%) Without Events (Censored)	11 (84.6%)	14 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	8.2 (NE, NE)	NE (3.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.423 (0.197, 10.282)
p-value			0.7251

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.9998
Race: White			
Total Patients	141	132	
Patients (%) With Events	6 (4.3%)	11 (8.3%)	
Patients (%) Without Events (Censored)	135 (95.7%)	121 (91.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.420 (0.154, 1.147)
p-value			0.0813
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.9999
Race: White			
Total Patients	141	132	
Patients (%) With Events	13 (9.2%)	7 (5.3%)	
Patients (%) Without Events (Censored)	128 (90.8%)	125 (94.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.673 (0.667, 4.193)
p-value			0.2678
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.9998
Race: White			
Total Patients	141	132	
Patients (%) With Events	9 (6.4%)	12 (9.1%)	
Patients (%) Without Events (Censored)	132 (93.6%)	120 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.547 (0.227, 1.318)
p-value			0.1728
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.7714
Race: White			
Total Patients	141	132	
Patients (%) With Events	59 (41.8%)	61 (46.2%)	
Patients (%) Without Events (Censored)	82 (58.2%)	71 (53.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.7 (3.2, NE)	3.3 (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.775 (0.541, 1.111)
p-value			0.1663
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	4 (30.8%)	5 (31.3%)	
Patients (%) Without Events (Censored)	9 (69.2%)	11 (68.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.3, NE)	5.1 (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.002 (0.267, 3.753)
p-value			0.9978

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.9914
Race: White			
Total Patients	141	132	
Patients (%) With Events	8 (5.7%)	10 (7.6%)	
Patients (%) Without Events (Censored)	133 (94.3%)	122 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.619 (0.243, 1.574)
p-value			0.3088
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	1 (6.3%)	
Patients (%) Without Events (Censored)	13 (100.0%)	15 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3674

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.9998
Race: White			
Total Patients	141	132	
Patients (%) With Events	7 (5.0%)	12 (9.1%)	
Patients (%) Without Events (Censored)	134 (95.0%)	120 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.385 (0.144, 1.031)
p-value			0.0492
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.3146
Race: White			
Total Patients	141	132	
Patients (%) With Events	65 (46.1%)	41 (31.1%)	
Patients (%) Without Events (Censored)	76 (53.9%)	91 (68.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.7 (2.8, NE)	10.1 (7.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.559 (1.053, 2.306)
p-value			0.0254
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	7 (53.8%)	3 (18.8%)	
Patients (%) Without Events (Censored)	6 (46.2%)	13 (81.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (0.5, NE)	NE (3.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.321 (0.855, 12.894)
p-value			0.0655

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.9996
Race: White			
Total Patients	141	132	
Patients (%) With Events	14 (9.9%)	2 (1.5%)	
Patients (%) Without Events (Censored)	127 (90.1%)	130 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.405 (1.455, 28.188)
p-value			0.0048
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.6858
Race: White			
Total Patients	141	132	
Patients (%) With Events	91 (64.5%)	57 (43.2%)	
Patients (%) Without Events (Censored)	50 (35.5%)	75 (56.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.7, 1.2)	5.5 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.935 (1.387, 2.699)
p-value			<0.0001
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	6 (46.2%)	6 (37.5%)	
Patients (%) Without Events (Censored)	7 (53.8%)	10 (62.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.3, NE)	8.2 (3.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.444 (0.464, 4.495)
p-value			0.5240

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.8259
Race: White			
Total Patients	141	132	
Patients (%) With Events	75 (53.2%)	31 (23.5%)	
Patients (%) Without Events (Censored)	66 (46.8%)	101 (76.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.925 (1.922, 4.450)
p-value			<0.0001
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	5 (38.5%)	3 (18.8%)	
Patients (%) Without Events (Censored)	8 (61.5%)	13 (81.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.375 (0.567, 9.953)
p-value			0.2223

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.9997
Race: White			
Total Patients	141	132	
Patients (%) With Events	3 (2.1%)	10 (7.6%)	
Patients (%) Without Events (Censored)	138 (97.9%)	122 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.233 (0.064, 0.851)
p-value			0.0166
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.5: Time to the First Frequent TEAE by SOC, PT and Subgroup: Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9909
Race: White			
Total Patients	141	132	
Patients (%) With Events	17 (12.1%)	3 (2.3%)	
Patients (%) Without Events (Censored)	124 (87.9%)	129 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.164 (1.511, 17.653)
p-value			0.0035
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	2 (15.4%)	0	
Patients (%) Without Events (Censored)	11 (84.6%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1152

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.6122
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	78 (89.7%)	57 (63.3%)	
Patients (%) Without Events (Censored)	9 (10.3%)	33 (36.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	1.6 (0.7, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.787 (1.264, 2.527)
p-value			0.0008
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	87 (76.3%)	61 (58.7%)	
Patients (%) Without Events (Censored)	27 (23.7%)	43 (41.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	1.7 (0.7, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.595 (1.148, 2.216)
p-value			0.0059

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.1147
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	38 (43.7%)	21 (23.3%)	
Patients (%) Without Events (Censored)	49 (56.3%)	69 (76.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (3.1, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.018 (1.183, 3.442)
p-value			0.0086
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	32 (28.1%)	24 (23.1%)	
Patients (%) Without Events (Censored)	82 (71.9%)	80 (76.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.6, NE)	NE (7.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.081 (0.635, 1.839)
p-value			0.7736

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.7293
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	68 (78.2%)	48 (53.3%)	
Patients (%) Without Events (Censored)	19 (21.8%)	42 (46.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	4.1 (0.7, 8.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.641 (1.130, 2.381)
p-value			0.0077
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	74 (64.9%)	53 (51.0%)	
Patients (%) Without Events (Censored)	40 (35.1%)	51 (49.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.2)	2.5 (1.6, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.510 (1.061, 2.150)
p-value			0.0241

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.5459
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	5 (5.7%)	7 (7.8%)	
Patients (%) Without Events (Censored)	82 (94.3%)	83 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.623 (0.197, 1.974)
p-value			0.4169
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	7 (6.1%)	14 (13.5%)	
Patients (%) Without Events (Censored)	107 (93.9%)	90 (86.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.424 (0.171, 1.054)
p-value			0.0567

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.7834
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	80 (92.0%)	61 (67.8%)	
Patients (%) Without Events (Censored)	7 (8.0%)	29 (32.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.4)	1.0 (0.7, 1.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.084 (1.483, 2.929)
p-value			<0.0001
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	106 (93.0%)	77 (74.0%)	
Patients (%) Without Events (Censored)	8 (7.0%)	27 (26.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.2 (0.1, 0.3)	0.5 (0.3, 1.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.827 (1.354, 2.465)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.2466
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	53 (60.9%)	20 (22.2%)	
Patients (%) Without Events (Censored)	34 (39.1%)	70 (77.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.9, 4.3)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.831 (2.286, 6.420)
p-value			<0.0001
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	67 (58.8%)	29 (27.9%)	
Patients (%) Without Events (Censored)	47 (41.2%)	75 (72.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.7 (1.0, 5.1)	8.5 (5.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.528 (1.633, 3.915)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.2533
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	51 (58.6%)	24 (26.7%)	
Patients (%) Without Events (Censored)	36 (41.4%)	66 (73.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.7, 20.7)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.723 (1.673, 4.432)
p-value			<0.0001
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	69 (60.5%)	40 (38.5%)	
Patients (%) Without Events (Censored)	45 (39.5%)	64 (61.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.3, 3.7)	7.6 (3.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.846 (1.249, 2.728)
p-value			0.0016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.3962
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	19 (21.8%)	8 (8.9%)	
Patients (%) Without Events (Censored)	68 (78.2%)	82 (91.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.284 (0.992, 5.256)
p-value			0.0460
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	31 (27.2%)	19 (18.3%)	
Patients (%) Without Events (Censored)	83 (72.8%)	85 (81.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	14.5 (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.423 (0.803, 2.520)
p-value			0.2222

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.5983
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	3 (3.4%)	5 (5.6%)	
Patients (%) Without Events (Censored)	84 (96.6%)	85 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.554 (0.131, 2.332)
p-value			0.4137
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	3 (2.6%)	8 (7.7%)	
Patients (%) Without Events (Censored)	111 (97.4%)	96 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.299 (0.079, 1.132)
p-value			0.0595

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.1427
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	13 (14.9%)	2 (2.2%)	
Patients (%) Without Events (Censored)	74 (85.1%)	88 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.760 (1.292, 25.670)
p-value			0.0095
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	11 (9.6%)	6 (5.8%)	
Patients (%) Without Events (Censored)	103 (90.4%)	98 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.653 (0.611, 4.470)
p-value			0.3172

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.9775
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	5 (5.7%)	8 (8.9%)	
Patients (%) Without Events (Censored)	82 (94.3%)	82 (91.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.536 (0.174, 1.648)
p-value			0.2692
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	6 (5.3%)	9 (8.7%)	
Patients (%) Without Events (Censored)	108 (94.7%)	95 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.446 (0.155, 1.282)
p-value			0.1246

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.7982
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	33 (37.9%)	39 (43.3%)	
Patients (%) Without Events (Censored)	54 (62.1%)	51 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.8, NE)	4.6 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.771 (0.484, 1.227)
p-value			0.2688
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	41 (36.0%)	45 (43.3%)	
Patients (%) Without Events (Censored)	73 (64.0%)	59 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.7 (6.1, NE)	3.6 (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.693 (0.453, 1.061)
p-value			0.0895

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.4668
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	4 (4.6%)	6 (6.7%)	
Patients (%) Without Events (Censored)	83 (95.4%)	84 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.602 (0.170, 2.140)
p-value			0.4266
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	5 (4.4%)	12 (11.5%)	
Patients (%) Without Events (Censored)	109 (95.6%)	92 (88.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.286 (0.100, 0.816)
p-value			0.0129

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.7906
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	3 (3.4%)	7 (7.8%)	
Patients (%) Without Events (Censored)	84 (96.6%)	83 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.355 (0.091, 1.379)
p-value			0.1184
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	4 (3.5%)	7 (6.7%)	
Patients (%) Without Events (Censored)	110 (96.5%)	97 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.354 (0.091, 1.369)
p-value			0.1159

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.8275
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	31 (35.6%)	21 (23.3%)	
Patients (%) Without Events (Censored)	56 (64.4%)	69 (76.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.9 (3.9, NE)	10.1 (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.491 (0.855, 2.600)
p-value			0.1574
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	55 (48.2%)	38 (36.5%)	
Patients (%) Without Events (Censored)	59 (51.8%)	66 (63.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.7 (2.5, 10.5)	8.3 (3.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.388 (0.917, 2.099)
p-value			0.1209

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.4113
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	8 (9.2%)	1 (1.1%)	
Patients (%) Without Events (Censored)	79 (90.8%)	89 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.854 (0.849, 55.351)
p-value			0.0366
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	9 (7.9%)	3 (2.9%)	
Patients (%) Without Events (Censored)	105 (92.1%)	101 (97.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.662 (0.720, 9.849)
p-value			0.1272

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.1783
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	59 (67.8%)	38 (42.2%)	
Patients (%) Without Events (Censored)	28 (32.2%)	52 (57.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.5, 1.8)	5.7 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.262 (1.500, 3.410)
p-value			<0.0001
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	61 (53.5%)	41 (39.4%)	
Patients (%) Without Events (Censored)	53 (46.5%)	63 (60.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (0.7, 10.6)	5.5 (3.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.525 (1.026, 2.266)
p-value			0.0367

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.0556
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	49 (56.3%)	18 (20.0%)	
Patients (%) Without Events (Censored)	38 (43.7%)	72 (80.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.836 (2.231, 6.594)
p-value			<0.0001
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	49 (43.0%)	27 (26.0%)	
Patients (%) Without Events (Censored)	65 (57.0%)	77 (74.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.879 (1.174, 3.007)
p-value			0.0080

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.7122
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	3 (3.4%)	9 (10.0%)	
Patients (%) Without Events (Censored)	84 (96.6%)	81 (90.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.230 (0.060, 0.888)
p-value			0.0215
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	1 (0.9%)	5 (4.8%)	
Patients (%) Without Events (Censored)	113 (99.1%)	99 (95.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.166 (0.019, 1.425)
p-value			0.0623

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.6: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.3112
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	12 (13.8%)	1 (1.1%)	
Patients (%) Without Events (Censored)	75 (86.2%)	89 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			12.118 (1.573, 93.365)
p-value			0.0022
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	12 (10.5%)	3 (2.9%)	
Patients (%) Without Events (Censored)	102 (89.5%)	101 (97.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.553 (1.001, 12.604)
p-value			0.0363

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.0121
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	96 (78.0%)	80 (66.1%)	
Patients (%) Without Events (Censored)	27 (22.0%)	41 (33.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	1.6 (0.7, 2.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.348 (0.999, 1.818)
p-value			0.0486
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	69 (88.5%)	38 (52.1%)	
Patients (%) Without Events (Censored)	9 (11.5%)	35 (47.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, 0.7)	2.1 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.423 (1.626, 3.609)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.7055
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	47 (38.2%)	30 (24.8%)	
Patients (%) Without Events (Censored)	76 (61.8%)	91 (75.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (4.7, NE)	13.4 (7.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.567 (0.991, 2.480)
p-value			0.0531
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	23 (29.5%)	15 (20.5%)	
Patients (%) Without Events (Censored)	55 (70.5%)	58 (79.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.9, NE)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.386 (0.722, 2.660)
p-value			0.3253

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.0148
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	79 (64.2%)	67 (55.4%)	
Patients (%) Without Events (Censored)	44 (35.8%)	54 (44.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 1.6)	2.7 (1.0, 6.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.217 (0.878, 1.688)
p-value			0.2320
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	63 (80.8%)	34 (46.6%)	
Patients (%) Without Events (Censored)	15 (19.2%)	39 (53.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 0.7)	2.5 (0.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.332 (1.534, 3.544)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.0182
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	3 (2.4%)	15 (12.4%)	
Patients (%) Without Events (Censored)	120 (97.6%)	106 (87.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.163 (0.047, 0.566)
p-value			0.0011
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	9 (11.5%)	6 (8.2%)	
Patients (%) Without Events (Censored)	69 (88.5%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.311 (0.466, 3.687)
p-value			0.6075

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.8778
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	114 (92.7%)	85 (70.2%)	
Patients (%) Without Events (Censored)	9 (7.3%)	36 (29.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.6, 1.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.946 (1.460, 2.594)
p-value			<0.0001
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	72 (92.3%)	53 (72.6%)	
Patients (%) Without Events (Censored)	6 (7.7%)	20 (27.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.2 (0.1, 0.3)	0.7 (0.4, 1.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.966 (1.370, 2.822)
p-value			0.0002

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.1153
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	77 (62.6%)	27 (22.3%)	
Patients (%) Without Events (Censored)	46 (37.4%)	94 (77.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.0, 2.9)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.832 (2.467, 5.952)
p-value			<0.0001
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	43 (55.1%)	22 (30.1%)	
Patients (%) Without Events (Censored)	35 (44.9%)	51 (69.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.7 (1.0, 8.2)	NE (3.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.179 (1.302, 3.646)
p-value			0.0024

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.9908
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	68 (55.3%)	38 (31.4%)	
Patients (%) Without Events (Censored)	55 (44.7%)	83 (68.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.8, 9.1)	NE (6.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.153 (1.446, 3.206)
p-value			0.0001
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	52 (66.7%)	26 (35.6%)	
Patients (%) Without Events (Censored)	26 (33.3%)	47 (64.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.3, 1.7)	NE (3.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.152 (1.340, 3.454)
p-value			0.0011

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.0284
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	31 (25.2%)	11 (9.1%)	
Patients (%) Without Events (Censored)	92 (74.8%)	110 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.764 (1.387, 5.507)
p-value			0.0025
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	19 (24.4%)	16 (21.9%)	
Patients (%) Without Events (Censored)	59 (75.6%)	57 (78.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (23.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.943 (0.480, 1.852)
p-value			0.8670

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.4057
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	1 (0.8%)	5 (4.1%)	
Patients (%) Without Events (Censored)	122 (99.2%)	116 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.178 (0.021, 1.531)
p-value			0.0766
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	5 (6.4%)	8 (11.0%)	
Patients (%) Without Events (Censored)	73 (93.6%)	65 (89.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.462 (0.150, 1.426)
p-value			0.1693

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.0770
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	14 (11.4%)	2 (1.7%)	
Patients (%) Without Events (Censored)	109 (88.6%)	119 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.402 (1.449, 28.293)
p-value			0.0050
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	10 (12.8%)	6 (8.2%)	
Patients (%) Without Events (Censored)	68 (87.2%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.417 (0.514, 3.903)
p-value			0.4986

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.7707
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	7 (5.7%)	12 (9.9%)	
Patients (%) Without Events (Censored)	116 (94.3%)	109 (90.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.474 (0.185, 1.211)
p-value			0.1105
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	4 (5.1%)	5 (6.8%)	
Patients (%) Without Events (Censored)	74 (94.9%)	68 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.522 (0.138, 1.975)
p-value			0.3306

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.7744
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	42 (34.1%)	48 (39.7%)	
Patients (%) Without Events (Censored)	81 (65.9%)	73 (60.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.1, NE)	NE (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.742 (0.489, 1.126)
p-value			0.1584
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	32 (41.0%)	36 (49.3%)	
Patients (%) Without Events (Censored)	46 (59.0%)	37 (50.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.9 (2.6, NE)	2.8 (1.6, 5.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.686 (0.425, 1.107)
p-value			0.1212

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.5965
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	6 (4.9%)	11 (9.1%)	
Patients (%) Without Events (Censored)	117 (95.1%)	110 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.445 (0.163, 1.211)
p-value			0.1028
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	3 (3.8%)	7 (9.6%)	
Patients (%) Without Events (Censored)	75 (96.2%)	66 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.299 (0.077, 1.164)
p-value			0.0652

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.3952
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	6 (4.9%)	10 (8.3%)	
Patients (%) Without Events (Censored)	117 (95.1%)	111 (91.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.432 (0.147, 1.269)
p-value			0.1174
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	1 (1.3%)	4 (5.5%)	
Patients (%) Without Events (Censored)	77 (98.7%)	69 (94.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.188 (0.021, 1.686)
p-value			0.0946

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.1930
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	43 (35.0%)	35 (28.9%)	
Patients (%) Without Events (Censored)	80 (65.0%)	86 (71.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.9 (6.5, NE)	NE (8.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.189 (0.760, 1.861)
p-value			0.4498
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	43 (55.1%)	24 (32.9%)	
Patients (%) Without Events (Censored)	35 (44.9%)	49 (67.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.3 (1.6, 5.7)	8.0 (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.861 (1.128, 3.068)
p-value			0.0131

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.2557
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	13 (10.6%)	2 (1.7%)	
Patients (%) Without Events (Censored)	110 (89.4%)	119 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.989 (1.344, 26.682)
p-value			0.0076
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	4 (5.1%)	2 (2.7%)	
Patients (%) Without Events (Censored)	74 (94.9%)	71 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.706 (0.312, 9.344)
p-value			0.5330

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.2889
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	73 (59.3%)	45 (37.2%)	
Patients (%) Without Events (Censored)	50 (40.7%)	76 (62.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.5)	NE (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.096 (1.444, 3.042)
p-value			<0.0001
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	47 (60.3%)	34 (46.6%)	
Patients (%) Without Events (Censored)	31 (39.7%)	39 (53.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.5, 10.6)	4.0 (1.6, 8.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.452 (0.930, 2.269)
p-value			0.1024

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.6318
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	59 (48.0%)	29 (24.0%)	
Patients (%) Without Events (Censored)	64 (52.0%)	92 (76.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.2 (0.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.470 (1.582, 3.856)
p-value			<0.0001
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	39 (50.0%)	16 (21.9%)	
Patients (%) Without Events (Censored)	39 (50.0%)	57 (78.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.832 (1.581, 5.074)
p-value			0.0003

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.3038
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	3 (2.4%)	7 (5.8%)	
Patients (%) Without Events (Censored)	120 (97.6%)	114 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.311 (0.078, 1.232)
p-value			0.0803
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	1 (1.3%)	7 (9.6%)	
Patients (%) Without Events (Censored)	77 (98.7%)	66 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.107 (0.013, 0.870)
p-value			0.0109

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.7: Time to the First Frequent TEAE by SOC, PT and Subgroup: Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.5947
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	15 (12.2%)	2 (1.7%)	
Patients (%) Without Events (Censored)	108 (87.8%)	119 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.277 (1.662, 31.855)
p-value			0.0020
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	9 (11.5%)	2 (2.7%)	
Patients (%) Without Events (Censored)	69 (88.5%)	71 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.991 (0.860, 18.526)
p-value			0.0564

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.1669
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	91 (78.4%)	73 (61.3%)	
Patients (%) Without Events (Censored)	25 (21.6%)	46 (38.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.9)	1.7 (0.7, 2.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.462 (1.071, 1.995)
p-value			0.0149
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	71 (88.8%)	45 (61.6%)	
Patients (%) Without Events (Censored)	9 (11.3%)	28 (38.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, 0.7)	1.2 (0.7, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.037 (1.398, 2.969)
p-value			0.0002

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.3419
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	41 (35.3%)	23 (19.3%)	
Patients (%) Without Events (Censored)	75 (64.7%)	96 (80.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.747 (1.046, 2.916)
p-value			0.0312
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	29 (36.3%)	22 (30.1%)	
Patients (%) Without Events (Censored)	51 (63.8%)	51 (69.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (4.7, NE)	13.4 (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.209 (0.694, 2.105)
p-value			0.5202

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.1267
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	78 (67.2%)	64 (53.8%)	
Patients (%) Without Events (Censored)	38 (32.8%)	55 (46.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.7, 1.2)	2.4 (1.0, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.351 (0.969, 1.883)
p-value			0.0708
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	62 (77.5%)	37 (50.7%)	
Patients (%) Without Events (Censored)	18 (22.5%)	36 (49.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.4, 0.9)	4.2 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.987 (1.320, 2.990)
p-value			0.0010

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.8926
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	7 (6.0%)	13 (10.9%)	
Patients (%) Without Events (Censored)	109 (94.0%)	106 (89.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.445 (0.175, 1.128)
p-value			0.0803
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	5 (6.3%)	8 (11.0%)	
Patients (%) Without Events (Censored)	75 (93.8%)	65 (89.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.532 (0.174, 1.626)
p-value			0.2600

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.1542
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	108 (93.1%)	89 (74.8%)	
Patients (%) Without Events (Censored)	8 (6.9%)	30 (25.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.5, 1.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.754 (1.316, 2.338)
p-value			<0.0001
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	74 (92.5%)	47 (64.4%)	
Patients (%) Without Events (Censored)	6 (7.5%)	26 (35.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.2 (0.1, 0.3)	1.2 (0.3, 1.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.350 (1.618, 3.415)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.3947
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	71 (61.2%)	32 (26.9%)	
Patients (%) Without Events (Censored)	45 (38.8%)	87 (73.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (1.3, 3.4)	NE (5.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.759 (1.814, 4.199)
p-value			<0.0001
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	48 (60.0%)	17 (23.3%)	
Patients (%) Without Events (Censored)	32 (40.0%)	56 (76.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.5 (0.7, 5.1)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.634 (2.086, 6.329)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.0763
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	66 (56.9%)	45 (37.8%)	
Patients (%) Without Events (Censored)	50 (43.1%)	74 (62.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.3, 8.2)	7.6 (3.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.715 (1.172, 2.508)
p-value			0.0048
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	50 (62.5%)	18 (24.7%)	
Patients (%) Without Events (Censored)	30 (37.5%)	55 (75.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.9, 3.7)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.199 (1.864, 5.492)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.2952
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	28 (24.1%)	19 (16.0%)	
Patients (%) Without Events (Censored)	88 (75.9%)	100 (84.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.387 (0.772, 2.493)
p-value			0.2692
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	21 (26.3%)	8 (11.0%)	
Patients (%) Without Events (Censored)	59 (73.8%)	65 (89.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.351 (1.040, 5.317)
p-value			0.0345

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.3663
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	4 (3.4%)	6 (5.0%)	
Patients (%) Without Events (Censored)	112 (96.6%)	113 (95.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.585 (0.164, 2.088)
p-value			0.4031
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	2 (2.5%)	7 (9.6%)	
Patients (%) Without Events (Censored)	78 (97.5%)	66 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.228 (0.047, 1.104)
p-value			0.0448

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.7301
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	13 (11.2%)	4 (3.4%)	
Patients (%) Without Events (Censored)	103 (88.8%)	115 (96.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.1 (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.824 (0.908, 8.785)
p-value			0.0610
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	11 (13.8%)	4 (5.5%)	
Patients (%) Without Events (Censored)	69 (86.3%)	69 (94.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.480 (0.790, 7.788)
p-value			0.1076

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.5488
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	5 (4.3%)	10 (8.4%)	
Patients (%) Without Events (Censored)	111 (95.7%)	109 (91.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.319 (0.105, 0.968)
p-value			0.0346
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	5 (6.3%)	7 (9.6%)	
Patients (%) Without Events (Censored)	75 (93.8%)	66 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.608 (0.193, 1.918)
p-value			0.3920

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.6223
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	41 (35.3%)	50 (42.0%)	
Patients (%) Without Events (Censored)	75 (64.7%)	69 (58.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.6, NE)	3.6 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.654 (0.430, 0.996)
p-value			0.0461
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	32 (40.0%)	34 (46.6%)	
Patients (%) Without Events (Censored)	48 (60.0%)	39 (53.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.6, NE)	3.9 (1.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.793 (0.489, 1.286)
p-value			0.3435

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.3509
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	6 (5.2%)	10 (8.4%)	
Patients (%) Without Events (Censored)	110 (94.8%)	109 (91.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.510 (0.185, 1.407)
p-value			0.1839
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	2 (2.5%)	8 (11.0%)	
Patients (%) Without Events (Censored)	78 (97.5%)	65 (89.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.189 (0.040, 0.893)
p-value			0.0187

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.9052
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	4 (3.4%)	8 (6.7%)	
Patients (%) Without Events (Censored)	112 (96.6%)	111 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.419 (0.125, 1.403)
p-value			0.1461
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	3 (3.8%)	6 (8.2%)	
Patients (%) Without Events (Censored)	77 (96.3%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.272 (0.055, 1.347)
p-value			0.0875

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.8379
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	47 (40.5%)	34 (28.6%)	
Patients (%) Without Events (Censored)	69 (59.5%)	85 (71.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (3.9, NE)	11.0 (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.365 (0.875, 2.129)
p-value			0.1708
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	37 (46.3%)	24 (32.9%)	
Patients (%) Without Events (Censored)	43 (53.8%)	49 (67.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.7 (2.1, NE)	10.1 (5.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.515 (0.906, 2.534)
p-value			0.1121

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.2799
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	12 (10.3%)	2 (1.7%)	
Patients (%) Without Events (Censored)	104 (89.7%)	117 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.344 (1.182, 24.156)
p-value			0.0148
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	4 (5.0%)	2 (2.7%)	
Patients (%) Without Events (Censored)	76 (95.0%)	71 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.738 (0.318, 9.492)
p-value			0.5181

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.2588
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	66 (56.9%)	50 (42.0%)	
Patients (%) Without Events (Censored)	50 (43.1%)	69 (58.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, 2.5)	5.5 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.621 (1.121, 2.343)
p-value			0.0099
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	52 (65.0%)	29 (39.7%)	
Patients (%) Without Events (Censored)	28 (35.0%)	44 (60.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 4.0)	8.2 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.178 (1.380, 3.436)
p-value			0.0006

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.5688
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	57 (49.1%)	29 (24.4%)	
Patients (%) Without Events (Censored)	59 (50.9%)	90 (75.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (0.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.399 (1.533, 3.755)
p-value			<0.0001
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	39 (48.8%)	16 (21.9%)	
Patients (%) Without Events (Censored)	41 (51.3%)	57 (78.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.878 (1.607, 5.156)
p-value			0.0002

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.8: Time to the First Frequent TEAE by SOC, PT and Subgroup: Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.3761
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	12 (10.3%)	3 (2.5%)	
Patients (%) Without Events (Censored)	104 (89.7%)	116 (97.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.927 (1.106, 13.949)
p-value			0.0225
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	12 (15.0%)	1 (1.4%)	
Patients (%) Without Events (Censored)	68 (85.0%)	72 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			11.334 (1.474, 87.159)
p-value			0.0032

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.2419
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	12 (92.3%)	6 (42.9%)	
Patients (%) Without Events (Censored)	1 (7.7%)	8 (57.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 1.0)	NE (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.756 (1.024, 7.416)
p-value			0.0409
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	147 (81.2%)	111 (63.1%)	
Patients (%) Without Events (Censored)	34 (18.8%)	65 (36.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.7)	1.6 (0.7, 2.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.562 (1.218, 2.002)
p-value			0.0004

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.2930
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	4 (30.8%)	4 (28.6%)	
Patients (%) Without Events (Censored)	9 (69.2%)	10 (71.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.4, NE)	NE (1.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.802 (0.192, 3.358)
p-value			0.7610
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	65 (35.9%)	41 (23.3%)	
Patients (%) Without Events (Censored)	116 (64.1%)	135 (76.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.6, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.538 (1.040, 2.276)
p-value			0.0303

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.3351
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	10 (76.9%)	5 (35.7%)	
Patients (%) Without Events (Censored)	3 (23.1%)	9 (64.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 3.1)	NE (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.390 (0.813, 7.025)
p-value			0.1076
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	127 (70.2%)	95 (54.0%)	
Patients (%) Without Events (Censored)	54 (29.8%)	81 (46.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.5 (1.0, 4.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.483 (1.136, 1.937)
p-value			0.0035

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.7758
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	2 (14.3%)	
Patients (%) Without Events (Censored)	12 (92.3%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (1.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.511 (0.046, 5.643)
p-value			0.5766
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	11 (6.1%)	19 (10.8%)	
Patients (%) Without Events (Censored)	170 (93.9%)	157 (89.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.504 (0.240, 1.062)
p-value			0.0663

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.3464
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	12 (92.3%)	11 (78.6%)	
Patients (%) Without Events (Censored)	1 (7.7%)	3 (21.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.3)	0.4 (0.1, 1.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.499 (0.653, 3.437)
p-value			0.3833
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	168 (92.8%)	123 (69.9%)	
Patients (%) Without Events (Censored)	13 (7.2%)	53 (30.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.8 (0.7, 1.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.094 (1.650, 2.657)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.4440
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	7 (53.8%)	1 (7.1%)	
Patients (%) Without Events (Censored)	6 (46.2%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	8.2 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.456 (0.777, 53.663)
p-value			0.0475
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	108 (59.7%)	47 (26.7%)	
Patients (%) Without Events (Censored)	73 (40.3%)	129 (73.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.2, 2.9)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.954 (2.096, 4.164)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.9022
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	9 (69.2%)	4 (28.6%)	
Patients (%) Without Events (Censored)	4 (30.8%)	10 (71.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, NE)	NE (0.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.442 (0.732, 8.144)
p-value			0.1399
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	107 (59.1%)	57 (32.4%)	
Patients (%) Without Events (Censored)	74 (40.9%)	119 (67.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.8, 2.6)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.237 (1.621, 3.089)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.7762
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	5 (38.5%)	2 (14.3%)	
Patients (%) Without Events (Censored)	8 (61.5%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	8.2 (1.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.634 (0.285, 9.371)
p-value			0.5780
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	42 (23.2%)	24 (13.6%)	
Patients (%) Without Events (Censored)	139 (76.8%)	152 (86.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.661 (1.005, 2.747)
p-value			0.0454

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.9916
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3173
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	6 (3.3%)	12 (6.8%)	
Patients (%) Without Events (Censored)	175 (96.7%)	164 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.424 (0.158, 1.135)
p-value			0.0786

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.9915
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3576
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	21 (11.6%)	8 (4.5%)	
Patients (%) Without Events (Censored)	160 (88.4%)	168 (95.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.489 (1.102, 5.621)
p-value			0.0232

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.9997
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	10 (5.5%)	17 (9.7%)	
Patients (%) Without Events (Censored)	171 (94.5%)	159 (90.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.458 (0.208, 1.010)
p-value			0.0475

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.6252
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	4 (30.8%)	5 (35.7%)	
Patients (%) Without Events (Censored)	9 (69.2%)	9 (64.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.7, NE)	4.6 (0.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.354 (0.084, 1.480)
p-value			0.1432
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	68 (37.6%)	76 (43.2%)	
Patients (%) Without Events (Censored)	113 (62.4%)	100 (56.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.9 (6.1, NE)	3.9 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.767 (0.553, 1.066)
p-value			0.1130

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.6308
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	2 (14.3%)	
Patients (%) Without Events (Censored)	12 (92.3%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.1, NE)	4.6 (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.170 (0.014, 2.102)
p-value			0.1323
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	8 (4.4%)	16 (9.1%)	
Patients (%) Without Events (Censored)	173 (95.6%)	160 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.405 (0.173, 0.949)
p-value			0.0313

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.9913
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2980
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	7 (3.9%)	13 (7.4%)	
Patients (%) Without Events (Censored)	174 (96.1%)	163 (92.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.389 (0.148, 1.026)
p-value			0.0482

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.7492
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	8 (61.5%)	5 (35.7%)	
Patients (%) Without Events (Censored)	5 (38.5%)	9 (64.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.5 (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.445 (0.455, 4.590)
p-value			0.5295
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	76 (42.0%)	52 (29.5%)	
Patients (%) Without Events (Censored)	105 (58.0%)	124 (70.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.5 (3.9, NE)	11.0 (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.487 (1.044, 2.117)
p-value			0.0270

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.9932
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3367
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	16 (8.8%)	4 (2.3%)	
Patients (%) Without Events (Censored)	165 (91.2%)	172 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.599 (1.197, 10.817)
p-value			0.0148

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.5812
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	8 (61.5%)	6 (42.9%)	
Patients (%) Without Events (Censored)	5 (38.5%)	8 (57.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.8 (0.5, NE)	NE (0.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.117 (0.370, 3.373)
p-value			0.8433
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	107 (59.1%)	71 (40.3%)	
Patients (%) Without Events (Censored)	74 (40.9%)	105 (59.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.1)	5.7 (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.835 (1.358, 2.479)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.8832
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	7 (53.8%)	3 (21.4%)	
Patients (%) Without Events (Censored)	6 (46.2%)	11 (78.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.2 (0.5, NE)	NE (1.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.225 (0.546, 9.060)
p-value			0.2524
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	86 (47.5%)	42 (23.9%)	
Patients (%) Without Events (Censored)	95 (52.5%)	134 (76.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.450 (1.693, 3.545)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.9929
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	1 (7.1%)	
Patients (%) Without Events (Censored)	13 (100.0%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3173
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	3 (1.7%)	12 (6.8%)	
Patients (%) Without Events (Censored)	178 (98.3%)	164 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.207 (0.058, 0.736)
p-value			0.0072

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.9: Time to the First Frequent TEAE by SOC, PT and Subgroup: Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9883
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	3 (23.1%)	0	
Patients (%) Without Events (Censored)	10 (76.9%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2258
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	21 (11.6%)	3 (1.7%)	
Patients (%) Without Events (Censored)	160 (88.4%)	173 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.946 (2.071, 23.294)
p-value			0.0003

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.1563
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	147 (83.1%)	104 (60.8%)	
Patients (%) Without Events (Censored)	30 (16.9%)	67 (39.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	1.6 (0.7, 2.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.833 (1.421, 2.365)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	18 (75.0%)	14 (60.9%)	
Patients (%) Without Events (Censored)	6 (25.0%)	9 (39.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.4, 6.9)	2.1 (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.049 (0.518, 2.125)
p-value			0.9213

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.1353
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	62 (35.0%)	37 (21.6%)	
Patients (%) Without Events (Censored)	115 (65.0%)	134 (78.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.6, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.657 (1.102, 2.491)
p-value			0.0144
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	8 (33.3%)	8 (34.8%)	
Patients (%) Without Events (Censored)	16 (66.7%)	15 (65.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.0, NE)	NE (1.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.723 (0.269, 1.942)
p-value			0.5177

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.2427
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	129 (72.9%)	89 (52.0%)	
Patients (%) Without Events (Censored)	48 (27.1%)	82 (48.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 0.9)	2.5 (1.2, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.672 (1.274, 2.193)
p-value			0.0002
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	13 (54.2%)	12 (52.2%)	
Patients (%) Without Events (Censored)	11 (45.8%)	11 (47.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.7 (0.6, NE)	4.5 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.021 (0.464, 2.246)
p-value			0.9935

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.9857
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	10 (5.6%)	21 (12.3%)	
Patients (%) Without Events (Censored)	167 (94.4%)	150 (87.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.403 (0.189, 0.858)
p-value			0.0148
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	2 (8.3%)	0	
Patients (%) Without Events (Censored)	22 (91.7%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1617

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.2265
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	165 (93.2%)	119 (69.6%)	
Patients (%) Without Events (Censored)	12 (6.8%)	52 (30.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	1.0 (0.7, 1.2)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.059 (1.617, 2.623)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	21 (87.5%)	19 (82.6%)	
Patients (%) Without Events (Censored)	3 (12.5%)	4 (17.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.2 (0.1, 0.3)	0.3 (0.2, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.469 (0.786, 2.744)
p-value			0.2179

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9713
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	103 (58.2%)	42 (24.6%)	
Patients (%) Without Events (Censored)	74 (41.8%)	129 (75.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (1.3, 4.3)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.055 (2.133, 4.377)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	17 (70.8%)	7 (30.4%)	
Patients (%) Without Events (Censored)	7 (29.2%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.3, 2.8)	8.5 (4.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.963 (1.224, 7.174)
p-value			0.0115

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.9991
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	105 (59.3%)	56 (32.7%)	
Patients (%) Without Events (Censored)	72 (40.7%)	115 (67.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.8, 3.5)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.168 (1.566, 3.003)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	15 (62.5%)	8 (34.8%)	
Patients (%) Without Events (Censored)	9 (37.5%)	15 (65.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.3, NE)	NE (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.174 (0.921, 5.134)
p-value			0.0630

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.5201
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	41 (23.2%)	21 (12.3%)	
Patients (%) Without Events (Censored)	136 (76.8%)	150 (87.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.799 (1.061, 3.052)
p-value			0.0271
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	9 (37.5%)	6 (26.1%)	
Patients (%) Without Events (Censored)	15 (62.5%)	17 (73.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.278 (0.453, 3.606)
p-value			0.6352

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.6415
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	5 (2.8%)	12 (7.0%)	
Patients (%) Without Events (Censored)	172 (97.2%)	159 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.358 (0.125, 1.020)
p-value			0.0447
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	1 (4.2%)	1 (4.3%)	
Patients (%) Without Events (Censored)	23 (95.8%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.723 (0.044, 11.882)
p-value			0.8196

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.7822
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	20 (11.3%)	7 (4.1%)	
Patients (%) Without Events (Censored)	157 (88.7%)	164 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.549 (1.073, 6.053)
p-value			0.0280
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	4 (16.7%)	1 (4.3%)	
Patients (%) Without Events (Censored)	20 (83.3%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.620 (0.404, 32.465)
p-value			0.2203

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.6240
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	9 (5.1%)	13 (7.6%)	
Patients (%) Without Events (Censored)	168 (94.9%)	158 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.541 (0.229, 1.279)
p-value			0.1554
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	2 (8.3%)	4 (17.4%)	
Patients (%) Without Events (Censored)	22 (91.7%)	19 (82.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	9.9 (5.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.301 (0.054, 1.680)
p-value			0.1428

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.5993
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	64 (36.2%)	75 (43.9%)	
Patients (%) Without Events (Censored)	113 (63.8%)	96 (56.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.1, NE)	3.6 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.705 (0.504, 0.986)
p-value			0.0402
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	10 (41.7%)	9 (39.1%)	
Patients (%) Without Events (Censored)	14 (58.3%)	14 (60.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.9 (2.7, NE)	NE (1.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.879 (0.354, 2.180)
p-value			0.7869

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.8494
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	7 (4.0%)	15 (8.8%)	
Patients (%) Without Events (Censored)	170 (96.0%)	156 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.371 (0.151, 0.915)
p-value			0.0249
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	2 (8.3%)	3 (13.0%)	
Patients (%) Without Events (Censored)	22 (91.7%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.478 (0.079, 2.884)
p-value			0.4103

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.9997
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	7 (4.0%)	14 (8.2%)	
Patients (%) Without Events (Censored)	170 (96.0%)	157 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.356 (0.136, 0.928)
p-value			0.0275
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	24 (100.0%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.9958
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	75 (42.4%)	52 (30.4%)	
Patients (%) Without Events (Censored)	102 (57.6%)	119 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.5 (3.6, NE)	11.0 (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.445 (1.013, 2.059)
p-value			0.0411
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	11 (45.8%)	7 (30.4%)	
Patients (%) Without Events (Censored)	13 (54.2%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	10.5 (2.5, NE)	NE (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.361 (0.524, 3.533)
p-value			0.5291

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.9903
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	15 (8.5%)	4 (2.3%)	
Patients (%) Without Events (Censored)	162 (91.5%)	167 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.308 (1.091, 10.027)
p-value			0.0251
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	2 (8.3%)	0	
Patients (%) Without Events (Censored)	22 (91.7%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2112

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.1149
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	101 (57.1%)	71 (41.5%)	
Patients (%) Without Events (Censored)	76 (42.9%)	100 (58.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 2.4)	5.6 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.658 (1.223, 2.249)
p-value			0.0010
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	19 (79.2%)	8 (34.8%)	
Patients (%) Without Events (Censored)	5 (20.8%)	15 (65.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.5, 2.8)	NE (3.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.412 (1.486, 7.836)
p-value			0.0021

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.2646
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	84 (47.5%)	41 (24.0%)	
Patients (%) Without Events (Censored)	93 (52.5%)	130 (76.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.2 (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.400 (1.651, 3.489)
p-value			<0.0001
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	14 (58.3%)	4 (17.4%)	
Patients (%) Without Events (Censored)	10 (41.7%)	19 (82.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.5, NE)	NE (5.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.689 (1.538, 14.302)
p-value			0.0028

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.9901
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	4 (2.3%)	12 (7.0%)	
Patients (%) Without Events (Censored)	173 (97.7%)	159 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.231 (0.071, 0.750)
p-value			0.0084
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	0	2 (8.7%)	
Patients (%) Without Events (Censored)	24 (100.0%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1027

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.10: Time to the First Frequent TEAE by SOC, PT and Subgroup: Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9886
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	20 (11.3%)	4 (2.3%)	
Patients (%) Without Events (Censored)	157 (88.7%)	167 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.760 (1.625, 13.941)
p-value			0.0017
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	4 (16.7%)	0	
Patients (%) Without Events (Censored)	20 (83.3%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0532

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.5835
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	97 (79.5%)	76 (58.9%)	
Patients (%) Without Events (Censored)	25 (20.5%)	53 (41.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.8)	1.8 (0.8, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.749 (1.294, 2.365)
p-value			0.0003
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	68 (86.1%)	42 (64.6%)	
Patients (%) Without Events (Censored)	11 (13.9%)	23 (35.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	0.7 (0.5, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.462 (0.990, 2.159)
p-value			0.0577

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.3604
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	37 (30.3%)	29 (22.5%)	
Patients (%) Without Events (Censored)	85 (69.7%)	100 (77.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.9, NE)	NE (7.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.269 (0.780, 2.067)
p-value			0.3364
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	33 (41.8%)	16 (24.6%)	
Patients (%) Without Events (Censored)	46 (58.2%)	49 (75.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (3.4, NE)	13.4 (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.806 (0.993, 3.284)
p-value			0.0509

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.5164
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	82 (67.2%)	62 (48.1%)	
Patients (%) Without Events (Censored)	40 (32.8%)	67 (51.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.3)	4.2 (1.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.653 (1.188, 2.301)
p-value			0.0028
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	60 (75.9%)	39 (60.0%)	
Patients (%) Without Events (Censored)	19 (24.1%)	26 (40.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.0 (0.6, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.369 (0.913, 2.054)
p-value			0.1235

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.0993
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	8 (6.6%)	9 (7.0%)	
Patients (%) Without Events (Censored)	114 (93.4%)	120 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.875 (0.337, 2.273)
p-value			0.7823
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	4 (5.1%)	12 (18.5%)	
Patients (%) Without Events (Censored)	75 (94.9%)	53 (81.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (8.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.233 (0.075, 0.725)
p-value			0.0061

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.4050
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	113 (92.6%)	94 (72.9%)	
Patients (%) Without Events (Censored)	9 (7.4%)	35 (27.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	0.7 (0.4, 1.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.814 (1.373, 2.397)
p-value			<0.0001
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	73 (92.4%)	44 (67.7%)	
Patients (%) Without Events (Censored)	6 (7.6%)	21 (32.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.3)	1.0 (0.5, 1.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.267 (1.543, 3.331)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9246
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	73 (59.8%)	32 (24.8%)	
Patients (%) Without Events (Censored)	49 (40.2%)	97 (75.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.2, 4.3)	NE (6.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.091 (2.038, 4.687)
p-value			<0.0001
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	47 (59.5%)	17 (26.2%)	
Patients (%) Without Events (Censored)	32 (40.5%)	48 (73.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (0.8, 5.1)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.962 (1.698, 5.167)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.9122
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	75 (61.5%)	43 (33.3%)	
Patients (%) Without Events (Censored)	47 (38.5%)	86 (66.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.3, 2.6)	NE (6.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.226 (1.527, 3.244)
p-value			<0.0001
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	45 (57.0%)	21 (32.3%)	
Patients (%) Without Events (Censored)	34 (43.0%)	44 (67.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.7, 9.1)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.138 (1.272, 3.593)
p-value			0.0032

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.6556
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	31 (25.4%)	19 (14.7%)	
Patients (%) Without Events (Censored)	91 (74.6%)	110 (85.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.567 (0.880, 2.789)
p-value			0.1226
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	19 (24.1%)	8 (12.3%)	
Patients (%) Without Events (Censored)	60 (75.9%)	57 (87.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.946 (0.849, 4.461)
p-value			0.1095

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.7208
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	4 (3.3%)	8 (6.2%)	
Patients (%) Without Events (Censored)	118 (96.7%)	121 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.400 (0.118, 1.350)
p-value			0.1271
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	2 (2.5%)	5 (7.7%)	
Patients (%) Without Events (Censored)	77 (97.5%)	60 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.323 (0.063, 1.667)
p-value			0.1554

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.3015
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	12 (9.8%)	6 (4.7%)	
Patients (%) Without Events (Censored)	110 (90.2%)	123 (95.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.898 (0.701, 5.133)
p-value			0.1994
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	12 (15.2%)	2 (3.1%)	
Patients (%) Without Events (Censored)	67 (84.8%)	63 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.765 (1.065, 21.306)
p-value			0.0241

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.0881
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	9 (7.4%)	9 (7.0%)	
Patients (%) Without Events (Censored)	113 (92.6%)	120 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.790 (0.309, 2.020)
p-value			0.6199
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	2 (2.5%)	8 (12.3%)	
Patients (%) Without Events (Censored)	77 (97.5%)	57 (87.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.179 (0.038, 0.844)
p-value			0.0144

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.0470
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	51 (41.8%)	52 (40.3%)	
Patients (%) Without Events (Censored)	71 (58.2%)	77 (59.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.7 (3.1, NE)	5.1 (2.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.932 (0.632, 1.374)
p-value			0.7243
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	23 (29.1%)	32 (49.2%)	
Patients (%) Without Events (Censored)	56 (70.9%)	33 (50.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (9.3, NE)	3.6 (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.474 (0.277, 0.813)
p-value			0.0055

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.9471
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	4 (3.3%)	9 (7.0%)	
Patients (%) Without Events (Censored)	118 (96.7%)	120 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.347 (0.106, 1.135)
p-value			0.0672
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	5 (6.3%)	9 (13.8%)	
Patients (%) Without Events (Censored)	74 (93.7%)	56 (86.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.398 (0.133, 1.191)
p-value			0.0877

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.4540
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	4 (3.3%)	6 (4.7%)	
Patients (%) Without Events (Censored)	118 (96.7%)	123 (95.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.468 (0.117, 1.873)
p-value			0.2720
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	3 (3.8%)	8 (12.3%)	
Patients (%) Without Events (Censored)	76 (96.2%)	57 (87.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.262 (0.069, 0.992)
p-value			0.0341

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.8065
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	53 (43.4%)	40 (31.0%)	
Patients (%) Without Events (Censored)	69 (56.6%)	89 (69.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.5 (2.8, NE)	10.1 (5.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.415 (0.938, 2.135)
p-value			0.0980
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	33 (41.8%)	19 (29.2%)	
Patients (%) Without Events (Censored)	46 (58.2%)	46 (70.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	10.5 (3.4, NE)	NE (8.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.532 (0.871, 2.697)
p-value			0.1347

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.4919
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	11 (9.0%)	2 (1.6%)	
Patients (%) Without Events (Censored)	111 (91.0%)	127 (98.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.678 (1.258, 25.623)
p-value			0.0107
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	6 (7.6%)	2 (3.1%)	
Patients (%) Without Events (Censored)	73 (92.4%)	63 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.9 (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.263 (0.455, 11.250)
p-value			0.3049

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.0504
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	81 (66.4%)	50 (38.8%)	
Patients (%) Without Events (Censored)	41 (33.6%)	79 (61.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.6, 1.3)	8.7 (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.280 (1.601, 3.248)
p-value			<0.0001
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	39 (49.4%)	29 (44.6%)	
Patients (%) Without Events (Censored)	40 (50.6%)	36 (55.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (0.7, NE)	5.5 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.256 (0.776, 2.033)
p-value			0.3574

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.0524
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	68 (55.7%)	28 (21.7%)	
Patients (%) Without Events (Censored)	54 (44.3%)	101 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 9.2)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.366 (2.165, 5.232)
p-value			<0.0001
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	30 (38.0%)	17 (26.2%)	
Patients (%) Without Events (Censored)	49 (62.0%)	48 (73.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.636 (0.902, 2.969)
p-value			0.1046

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.5976
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	3 (2.5%)	9 (7.0%)	
Patients (%) Without Events (Censored)	119 (97.5%)	120 (93.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.262 (0.068, 1.012)
p-value			0.0383
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	1 (1.3%)	5 (7.7%)	
Patients (%) Without Events (Censored)	78 (98.7%)	60 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.131 (0.015, 1.131)
p-value			0.0297

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.11: Time to the First Frequent TEAE by SOC, PT and Subgroup: Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9856
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	17 (13.9%)	3 (2.3%)	
Patients (%) Without Events (Censored)	105 (86.1%)	126 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.603 (1.639, 19.158)
p-value			0.0020
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	7 (8.9%)	1 (1.5%)	
Patients (%) Without Events (Censored)	72 (91.1%)	64 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.081 (0.748, 49.432)
p-value			0.0540

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.2669
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	56 (82.4%)	49 (68.1%)	
Patients (%) Without Events (Censored)	12 (17.6%)	23 (31.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	0.8 (0.6, 2.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.509 (1.023, 2.226)
p-value			0.0424
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	58 (81.7%)	41 (55.4%)	
Patients (%) Without Events (Censored)	13 (18.3%)	33 (44.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.0)	2.0 (0.5, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.569 (1.049, 2.346)
p-value			0.0261
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	33 (82.5%)	16 (61.5%)	
Patients (%) Without Events (Censored)	7 (17.5%)	10 (38.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, 0.7)	2.1 (0.5, 8.5)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.101 (1.150, 3.838)
p-value			0.0148

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.5627
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	20 (29.4%)	20 (27.8%)	
Patients (%) Without Events (Censored)	48 (70.6%)	52 (72.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.6, NE)	13.4 (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.160 (0.622, 2.160)
p-value			0.6559
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	28 (39.4%)	15 (20.3%)	
Patients (%) Without Events (Censored)	43 (60.6%)	59 (79.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.9 (4.3, NE)	NE (6.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.661 (0.882, 3.126)
p-value			0.1121
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	14 (35.0%)	6 (23.1%)	
Patients (%) Without Events (Censored)	26 (65.0%)	20 (76.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.2, NE)	NE (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.576 (0.605, 4.102)
p-value			0.3473

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.4077
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	50 (73.5%)	44 (61.1%)	
Patients (%) Without Events (Censored)	18 (26.5%)	28 (38.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 1.0)	1.0 (0.7, 4.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.456 (0.968, 2.191)
p-value			0.0748
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	46 (64.8%)	34 (45.9%)	
Patients (%) Without Events (Censored)	25 (35.2%)	40 (54.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.7, 2.6)	4.9 (1.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.376 (0.882, 2.145)
p-value			0.1515
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	30 (75.0%)	14 (53.8%)	
Patients (%) Without Events (Censored)	10 (25.0%)	12 (46.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 1.0)	4.2 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.964 (1.038, 3.716)
p-value			0.0349

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.9847
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	0	13 (18.1%)	
Patients (%) Without Events (Censored)	68 (100.0%)	59 (81.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (8.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0002
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	6 (8.5%)	5 (6.8%)	
Patients (%) Without Events (Censored)	65 (91.5%)	69 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.057 (0.318, 3.513)
p-value			0.9279
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	4 (10.0%)	1 (3.8%)	
Patients (%) Without Events (Censored)	36 (90.0%)	25 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.667 (0.298, 23.871)
p-value			0.3613

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.7187
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	61 (89.7%)	53 (73.6%)	
Patients (%) Without Events (Censored)	7 (10.3%)	19 (26.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.4)	0.8 (0.3, 1.3)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.775 (1.221, 2.582)
p-value			0.0025
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	65 (91.5%)	48 (64.9%)	
Patients (%) Without Events (Censored)	6 (8.5%)	26 (35.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.1, 0.3)	0.8 (0.5, 2.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.996 (1.365, 2.920)
p-value			0.0003
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	38 (95.0%)	22 (84.6%)	
Patients (%) Without Events (Censored)	2 (5.0%)	4 (15.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.5)	0.7 (0.3, 1.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.713 (0.999, 2.937)
p-value			0.0495

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.4025
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	33 (48.5%)	17 (23.6%)	
Patients (%) Without Events (Censored)	35 (51.5%)	55 (76.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.0 (0.7, NE)	NE (7.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.565 (1.427, 4.610)
p-value			0.0011
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	45 (63.4%)	14 (18.9%)	
Patients (%) Without Events (Censored)	26 (36.6%)	60 (81.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.7, 3.6)	NE (5.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.236 (2.321, 7.730)
p-value			<0.0001
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	25 (62.5%)	11 (42.3%)	
Patients (%) Without Events (Censored)	15 (37.5%)	15 (57.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.4 (1.0, 8.2)	6.7 (1.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.809 (0.883, 3.708)
p-value			0.1002

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.7346
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	37 (54.4%)	24 (33.3%)	
Patients (%) Without Events (Censored)	31 (45.6%)	48 (66.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.3, NE)	NE (6.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.183 (1.303, 3.657)
p-value			0.0024
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	46 (64.8%)	22 (29.7%)	
Patients (%) Without Events (Censored)	25 (35.2%)	52 (70.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.3, 2.6)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.557 (1.535, 4.261)
p-value			0.0002
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	22 (55.0%)	9 (34.6%)	
Patients (%) Without Events (Censored)	18 (45.0%)	17 (65.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.0 (0.3, NE)	NE (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.784 (0.816, 3.899)
p-value			0.1401

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Source: .../germandossier/jan2023/prog/t-ttae-frq-subgrp-exg.sas v9.4 Output file: t-ttae-frq-sgrp-exg12.pdf 09MAY2023:11:02 Page 14 of 34

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.4365
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	13 (19.1%)	12 (16.7%)	
Patients (%) Without Events (Censored)	55 (80.9%)	60 (83.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.189 (0.542, 2.606)
p-value			0.6661
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	19 (26.8%)	9 (12.2%)	
Patients (%) Without Events (Censored)	52 (73.2%)	65 (87.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.928 (0.864, 4.304)
p-value			0.1017
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	12 (30.0%)	4 (15.4%)	
Patients (%) Without Events (Censored)	28 (70.0%)	22 (84.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.151 (0.693, 6.677)
p-value			0.1743

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.8490
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	6 (8.8%)	2 (2.8%)	
Patients (%) Without Events (Censored)	62 (91.2%)	70 (97.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.142 (0.634, 15.581)
p-value			0.1389
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	12 (16.9%)	5 (6.8%)	
Patients (%) Without Events (Censored)	59 (83.1%)	69 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.1 (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.986 (0.686, 5.745)
p-value			0.1967
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	4 (10.0%)	1 (3.8%)	
Patients (%) Without Events (Censored)	36 (90.0%)	25 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.713 (0.303, 24.278)
p-value			0.3500

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.3266
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	3 (4.4%)	5 (6.9%)	
Patients (%) Without Events (Censored)	65 (95.6%)	67 (93.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.497 (0.116, 2.131)
p-value			0.3377
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	5 (7.0%)	6 (8.1%)	
Patients (%) Without Events (Censored)	66 (93.0%)	68 (91.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.595 (0.177, 2.000)
p-value			0.3985
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	1 (2.5%)	4 (15.4%)	
Patients (%) Without Events (Censored)	39 (97.5%)	22 (84.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.162 (0.018, 1.455)
p-value			0.0633

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.0316
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	19 (27.9%)	34 (47.2%)	
Patients (%) Without Events (Censored)	49 (72.1%)	38 (52.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (9.7, NE)	3.2 (1.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.516 (0.294, 0.908)
p-value			0.0193
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	24 (33.8%)	29 (39.2%)	
Patients (%) Without Events (Censored)	47 (66.2%)	45 (60.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.1, NE)	3.6 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.626 (0.359, 1.090)
p-value			0.0965
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	22 (55.0%)	11 (42.3%)	
Patients (%) Without Events (Censored)	18 (45.0%)	15 (57.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.8 (1.2, NE)	4.6 (1.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.405 (0.681, 2.900)
p-value			0.3568

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.2320
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	2 (2.9%)	8 (11.1%)	
Patients (%) Without Events (Censored)	66 (97.1%)	64 (88.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.241 (0.051, 1.139)
p-value			0.0516
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	3 (4.2%)	6 (8.1%)	
Patients (%) Without Events (Censored)	68 (95.8%)	68 (91.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.312 (0.077, 1.270)
p-value			0.0866
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	4 (10.0%)	3 (11.5%)	
Patients (%) Without Events (Censored)	36 (90.0%)	23 (88.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (9.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.892 (0.200, 3.987)
p-value			0.8752

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.5298
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	26 (38.2%)	18 (25.0%)	
Patients (%) Without Events (Censored)	42 (61.8%)	54 (75.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.9 (3.3, NE)	NE (7.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.812 (0.993, 3.309)
p-value			0.0502
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	27 (38.0%)	22 (29.7%)	
Patients (%) Without Events (Censored)	44 (62.0%)	52 (70.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.9 (2.8, NE)	8.0 (5.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.064 (0.601, 1.881)
p-value			0.8332
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	22 (55.0%)	12 (46.2%)	
Patients (%) Without Events (Censored)	18 (45.0%)	14 (53.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	4.6 (0.7, 10.5)	10.1 (3.5, 11.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.299 (0.641, 2.633)
p-value			0.4683

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.9925
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	4 (5.9%)	2 (2.8%)	
Patients (%) Without Events (Censored)	64 (94.1%)	70 (97.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.140 (0.392, 11.686)
p-value			0.3680
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	8 (11.3%)	2 (2.7%)	
Patients (%) Without Events (Censored)	63 (88.7%)	72 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.156 (0.653, 15.241)
p-value			0.1312
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	4 (10.0%)	0	
Patients (%) Without Events (Censored)	36 (90.0%)	26 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0939

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.2867
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	39 (57.4%)	28 (38.9%)	
Patients (%) Without Events (Censored)	29 (42.6%)	44 (61.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, 10.6)	8.2 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.008 (1.234, 3.268)
p-value			0.0042
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	44 (62.0%)	25 (33.8%)	
Patients (%) Without Events (Censored)	27 (38.0%)	49 (66.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.5 (0.7, 2.8)	NE (5.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.076 (1.267, 3.400)
p-value			0.0032
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	24 (60.0%)	15 (57.7%)	
Patients (%) Without Events (Censored)	16 (40.0%)	11 (42.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 14.3)	3.5 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.330 (0.696, 2.541)
p-value			0.3824

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.7611
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	30 (44.1%)	16 (22.2%)	
Patients (%) Without Events (Censored)	38 (55.9%)	56 (77.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.2 (1.0, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.397 (1.305, 4.402)
p-value			0.0036
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	37 (52.1%)	17 (23.0%)	
Patients (%) Without Events (Censored)	34 (47.9%)	57 (77.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (0.7, NE)	NE (5.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.730 (1.534, 4.860)
p-value			0.0004
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	20 (50.0%)	8 (30.8%)	
Patients (%) Without Events (Censored)	20 (50.0%)	18 (69.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.134 (0.937, 4.858)
p-value			0.0633

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9862
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	9 (13.2%)	0	
Patients (%) Without Events (Censored)	59 (86.8%)	72 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0016
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	8 (11.3%)	2 (2.7%)	
Patients (%) Without Events (Censored)	63 (88.7%)	72 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.010 (0.851, 18.893)
p-value			0.0570
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.12: Time to the First Frequent TEAE by SOC, PT and Subgroup: Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	4 (10.0%)	2 (7.7%)	
Patients (%) Without Events (Censored)	36 (90.0%)	24 (92.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.338 (0.245, 7.318)
p-value			0.7364

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.0018
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	17 (81.0%)	7 (30.4%)	
Patients (%) Without Events (Censored)	4 (19.0%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 0.7)	NE (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.068 (2.435, 15.118)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	104 (82.5%)	74 (61.7%)	
Patients (%) Without Events (Censored)	22 (17.5%)	46 (38.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.5, 0.7)	1.6 (0.7, 3.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.609 (1.191, 2.175)
p-value			0.0014
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	44 (81.5%)	37 (72.5%)	
Patients (%) Without Events (Censored)	10 (18.5%)	14 (27.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.3, 1.0)	0.7 (0.5, 0.8)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.050 (0.675, 1.633)
p-value			0.8627

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.0029
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	11 (52.4%)	3 (13.0%)	
Patients (%) Without Events (Censored)	10 (47.6%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	5.2 (1.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.136 (1.425, 18.510)
p-value			0.0055
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	45 (35.7%)	26 (21.7%)	
Patients (%) Without Events (Censored)	81 (64.3%)	94 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.4 (6.3, NE)	NE (13.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.749 (1.078, 2.837)
p-value			0.0221
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	14 (25.9%)	16 (31.4%)	
Patients (%) Without Events (Censored)	40 (74.1%)	35 (68.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	3.7 (2.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.633 (0.305, 1.315)
p-value			0.2167

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.0012
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	16 (76.2%)	5 (21.7%)	
Patients (%) Without Events (Censored)	5 (23.8%)	18 (78.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.4, 1.0)	NE (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.844 (2.460, 19.045)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	87 (69.0%)	63 (52.5%)	
Patients (%) Without Events (Censored)	39 (31.0%)	57 (47.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.7, 1.1)	4.1 (1.6, 7.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.484 (1.071, 2.056)
p-value			0.0144
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	39 (72.2%)	33 (64.7%)	
Patients (%) Without Events (Censored)	15 (27.8%)	18 (35.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.6, 1.6)	0.7 (0.5, 1.9)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.989 (0.618, 1.581)
p-value			0.9608

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Thrombocytopenia			
Interaction p-value			0.9870
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	3 (13.0%)	
Patients (%) Without Events (Censored)	21 (100.0%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0942
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	10 (7.9%)	15 (12.5%)	
Patients (%) Without Events (Censored)	116 (92.1%)	105 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.608 (0.273, 1.354)
p-value			0.2182
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	2 (3.7%)	3 (5.9%)	
Patients (%) Without Events (Censored)	52 (96.3%)	48 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.492 (0.080, 3.013)
p-value			0.4338

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.2120
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	21 (100.0%)	22 (95.7%)	
Patients (%) Without Events (Censored)	0	1 (4.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.0, 0.1)	0.3 (0.1, 0.7)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.835 (1.460, 5.506)
p-value			0.0020
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	114 (90.5%)	82 (68.3%)	
Patients (%) Without Events (Censored)	12 (9.5%)	38 (31.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.2, 0.3)	1.0 (0.8, 1.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.036 (1.522, 2.722)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	51 (94.4%)	34 (66.7%)	
Patients (%) Without Events (Censored)	3 (5.6%)	17 (33.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.3 (0.3, 0.6)	0.5 (0.3, 1.4)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.703 (1.097, 2.643)
p-value			0.0154

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.7939
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	13 (61.9%)	11 (47.8%)	
Patients (%) Without Events (Censored)	8 (38.1%)	12 (52.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.5 (0.3, NE)	6.7 (2.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.746 (0.777, 3.923)
p-value			0.1718
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	75 (59.5%)	24 (20.0%)	
Patients (%) Without Events (Censored)	51 (40.5%)	96 (80.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.0, 3.6)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.240 (2.673, 6.728)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	32 (59.3%)	14 (27.5%)	
Patients (%) Without Events (Censored)	22 (40.7%)	37 (72.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (1.2, 8.2)	4.9 (2.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.998 (1.053, 3.791)
p-value			0.0311

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Nausea			
Interaction p-value			0.7473
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	14 (66.7%)	13 (56.5%)	
Patients (%) Without Events (Censored)	7 (33.3%)	10 (43.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.1 (0.0, NE)	3.8 (0.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.939 (0.893, 4.210)
p-value			0.1012
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	72 (57.1%)	36 (30.0%)	
Patients (%) Without Events (Censored)	54 (42.9%)	84 (70.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.7, 6.0)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.307 (1.544, 3.448)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	34 (63.0%)	15 (29.4%)	
Patients (%) Without Events (Censored)	20 (37.0%)	36 (70.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.8, 3.7)	NE (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.306 (1.251, 4.252)
p-value			0.0056

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Vomiting			
Interaction p-value			0.6268
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	6 (28.6%)	4 (17.4%)	
Patients (%) Without Events (Censored)	15 (71.4%)	19 (82.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.953 (0.548, 6.960)
p-value			0.2939
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	30 (23.8%)	15 (12.5%)	
Patients (%) Without Events (Censored)	96 (76.2%)	105 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (14.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.918 (1.032, 3.566)
p-value			0.0355
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	14 (25.9%)	8 (15.7%)	
Patients (%) Without Events (Censored)	40 (74.1%)	43 (84.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	23.0 (16.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.121 (0.451, 2.785)
p-value			0.8033

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hyperglycaemia			
Interaction p-value			0.9904
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	2 (8.7%)	
Patients (%) Without Events (Censored)	21 (100.0%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1718
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	4 (3.2%)	11 (9.2%)	
Patients (%) Without Events (Censored)	122 (96.8%)	109 (90.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.328 (0.104, 1.031)
p-value			0.0448
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	2 (3.7%)	0	
Patients (%) Without Events (Censored)	52 (96.3%)	51 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.5351

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Hypokalaemia			
Interaction p-value			0.3258
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	6 (28.6%)	1 (4.3%)	
Patients (%) Without Events (Censored)	15 (71.4%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.980 (0.840, 58.021)
p-value			0.0363
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	16 (12.7%)	6 (5.0%)	
Patients (%) Without Events (Censored)	110 (87.3%)	114 (95.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.633 (1.030, 6.730)
p-value			0.0356
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	2 (3.7%)	1 (2.0%)	
Patients (%) Without Events (Censored)	52 (96.3%)	50 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	20.1 (20.1, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.926 (0.058, 14.797)
p-value			0.9564

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Myalgia			
Interaction p-value			0.9894
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	1 (4.3%)	
Patients (%) Without Events (Censored)	21 (100.0%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3042
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	3 (2.4%)	11 (9.2%)	
Patients (%) Without Events (Censored)	123 (97.6%)	109 (90.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.213 (0.059, 0.769)
p-value			0.0094
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	8 (14.8%)	5 (9.8%)	
Patients (%) Without Events (Censored)	46 (85.2%)	46 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (12.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.937 (0.289, 3.040)
p-value			0.9162

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.7888
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	7 (33.3%)	9 (39.1%)	
Patients (%) Without Events (Censored)	14 (66.7%)	14 (60.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.1, NE)	NE (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.809 (0.300, 2.179)
p-value			0.6708
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	45 (35.7%)	58 (48.3%)	
Patients (%) Without Events (Censored)	81 (64.3%)	62 (51.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.9 (6.1, NE)	3.6 (2.6, 5.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.602 (0.407, 0.892)
p-value			0.0107
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	22 (40.7%)	17 (33.3%)	
Patients (%) Without Events (Censored)	32 (59.3%)	34 (66.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.1, NE)	NE (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.125 (0.595, 2.130)
p-value			0.7232

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neuropathy peripheral			
Interaction p-value			0.9901
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	1 (4.3%)	
Patients (%) Without Events (Censored)	21 (100.0%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3286
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	8 (6.3%)	15 (12.5%)	
Patients (%) Without Events (Censored)	118 (93.7%)	105 (87.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.462 (0.196, 1.093)
p-value			0.0714
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	1 (1.9%)	2 (3.9%)	
Patients (%) Without Events (Censored)	53 (98.1%)	49 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.226 (0.016, 3.127)
p-value			0.2421

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Paraesthesia			
Interaction p-value			0.9896
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	2 (8.7%)	
Patients (%) Without Events (Censored)	21 (100.0%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1763
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	4 (3.2%)	10 (8.3%)	
Patients (%) Without Events (Censored)	122 (96.8%)	110 (91.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (18.8, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.265 (0.073, 0.962)
p-value			0.0302
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (5.6%)	2 (3.9%)	
Patients (%) Without Events (Censored)	51 (94.4%)	49 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.836 (0.134, 5.219)
p-value			0.8479

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.5778
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	8 (38.1%)	7 (30.4%)	
Patients (%) Without Events (Censored)	13 (61.9%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (2.1, NE)	8.3 (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.839 (0.658, 5.135)
p-value			0.2398
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	55 (43.7%)	44 (36.7%)	
Patients (%) Without Events (Censored)	71 (56.3%)	76 (63.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.3 (3.8, NE)	11.0 (4.2, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.210 (0.813, 1.799)
p-value			0.3454
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	23 (42.6%)	8 (15.7%)	
Patients (%) Without Events (Censored)	31 (57.4%)	43 (84.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	7.2 (2.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.693 (1.199, 6.048)
p-value			0.0127

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Epistaxis			
Interaction p-value			0.9781
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	1 (4.3%)	
Patients (%) Without Events (Censored)	18 (85.7%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (8.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.494 (0.363, 33.662)
p-value			0.2486
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	9 (7.1%)	2 (1.7%)	
Patients (%) Without Events (Censored)	117 (92.9%)	118 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (20.9, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.963 (0.848, 18.513)
p-value			0.0590
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	5 (9.3%)	1 (2.0%)	
Patients (%) Without Events (Censored)	49 (90.7%)	50 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.202 (0.486, 36.301)
p-value			0.1565

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Skin and subcutaneous tissue disorders			
Interaction p-value			0.0004
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	12 (57.1%)	17 (73.9%)	
Patients (%) Without Events (Censored)	9 (42.9%)	6 (26.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.5, NE)	1.7 (0.7, 3.0)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.767 (0.365, 1.610)
p-value			0.4735
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	71 (56.3%)	52 (43.3%)	
Patients (%) Without Events (Censored)	55 (43.7%)	68 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.5 (0.7, 6.3)	5.7 (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.602 (1.119, 2.293)
p-value			0.0093
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	37 (68.5%)	10 (19.6%)	
Patients (%) Without Events (Censored)	17 (31.5%)	41 (80.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.7 (0.6, 2.0)	NE (3.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.688 (2.325, 9.454)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Alopecia			
Interaction p-value			0.7420
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	11 (52.4%)	2 (8.7%)	
Patients (%) Without Events (Censored)	10 (47.6%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.1 (0.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			8.236 (1.818, 37.319)
p-value			0.0012
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	59 (46.8%)	40 (33.3%)	
Patients (%) Without Events (Censored)	67 (53.2%)	80 (66.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	9.2 (0.9, NE)	NE (5.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.649 (1.103, 2.464)
p-value			0.0140
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	28 (51.9%)	3 (5.9%)	
Patients (%) Without Events (Censored)	26 (48.1%)	48 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			11.415 (3.464, 37.614)
p-value			<0.0001

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Palmar-plantar erythrodysaesthesia syndrome			
Interaction p-value			0.9906
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	13 (56.5%)	
Patients (%) Without Events (Censored)	21 (100.0%)	10 (43.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	2.8 (0.9, 3.1)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	1 (0.8%)	1 (0.8%)	
Patients (%) Without Events (Censored)	125 (99.2%)	119 (99.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.718 (0.045, 11.480)
p-value			0.8139
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (5.6%)	0	
Patients (%) Without Events (Censored)	51 (94.4%)	51 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (16.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1843

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Pruritus			
Interaction p-value			0.9888
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	1 (4.3%)	
Patients (%) Without Events (Censored)	21 (100.0%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (10.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.6171
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	14 (11.1%)	3 (2.5%)	
Patients (%) Without Events (Censored)	112 (88.9%)	117 (97.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.586 (1.318, 15.965)
p-value			0.0085
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.2.13: Time to the First Frequent TEAE by SOC, PT and Subgroup: Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	10 (18.5%)	0	
Patients (%) Without Events (Censored)	44 (81.5%)	51 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0035

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients in at least one treatment arm is no less than 10.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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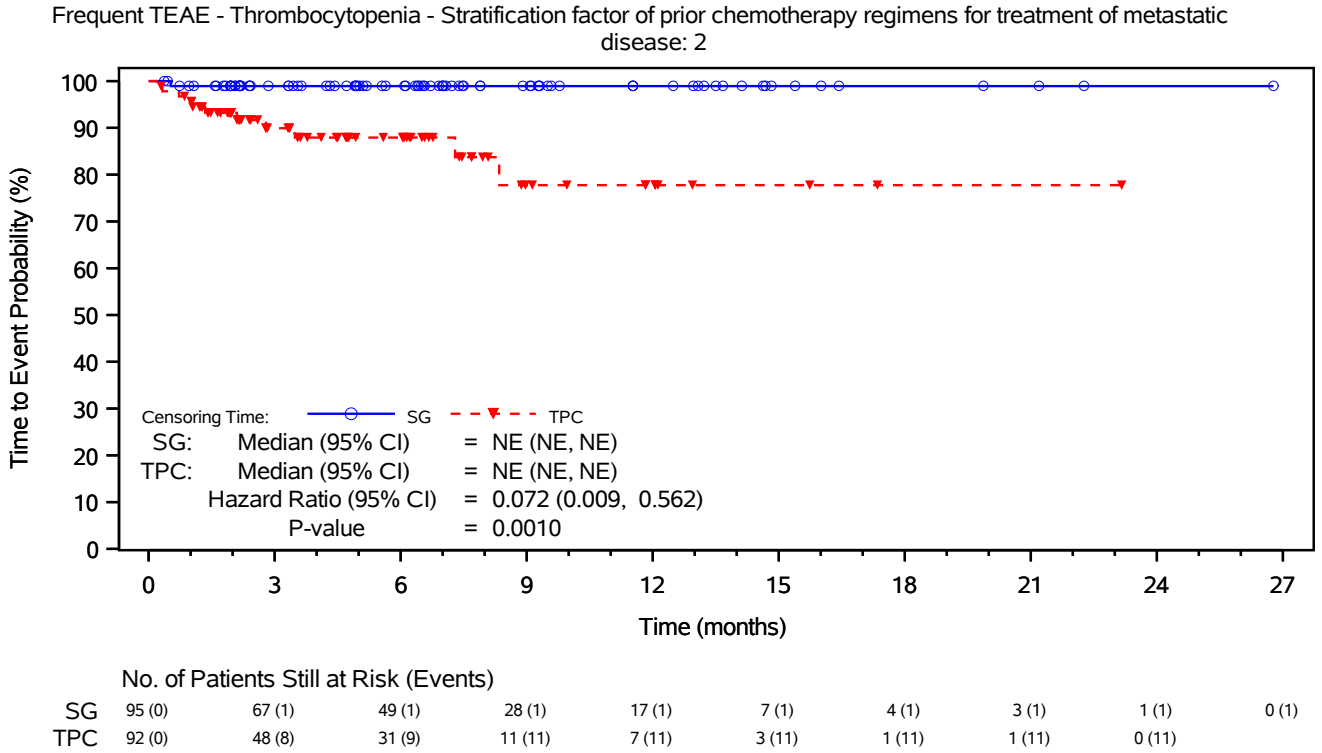
Figure 15.11.7.2.1: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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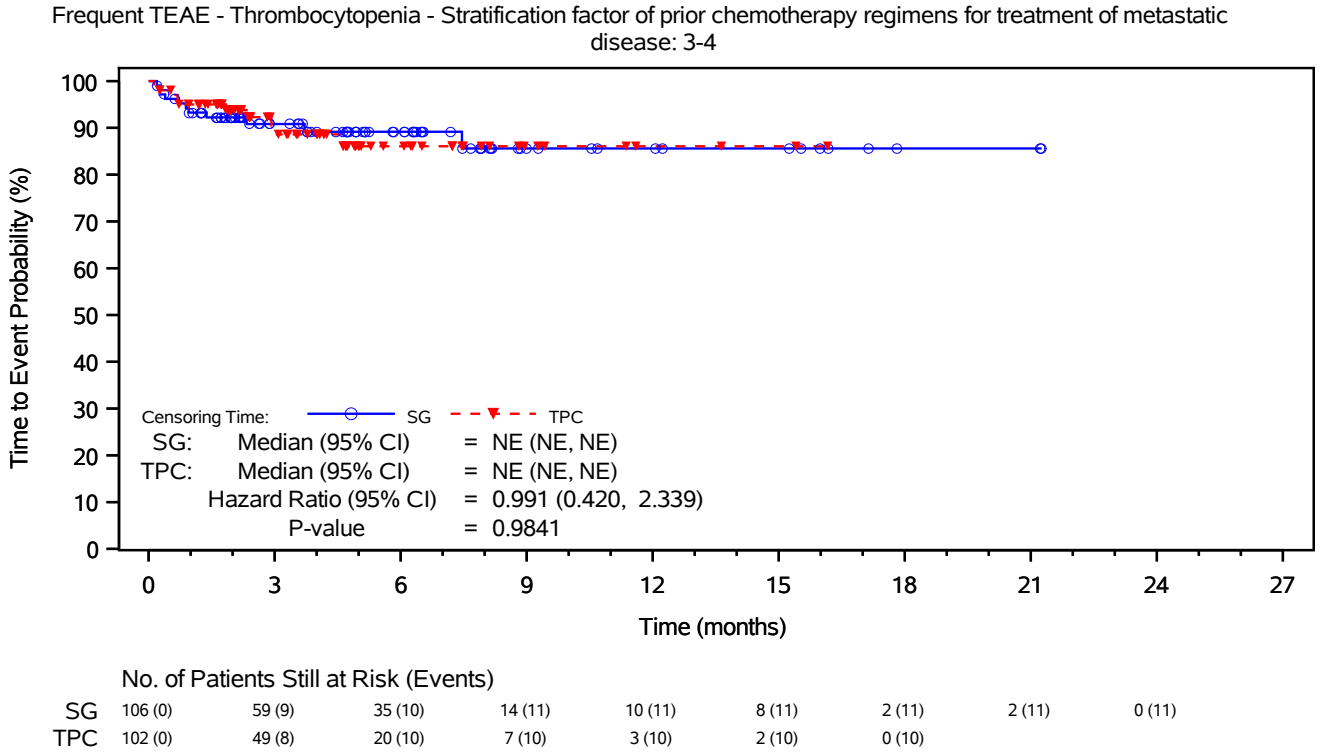
Figure 15.11.7.2.1: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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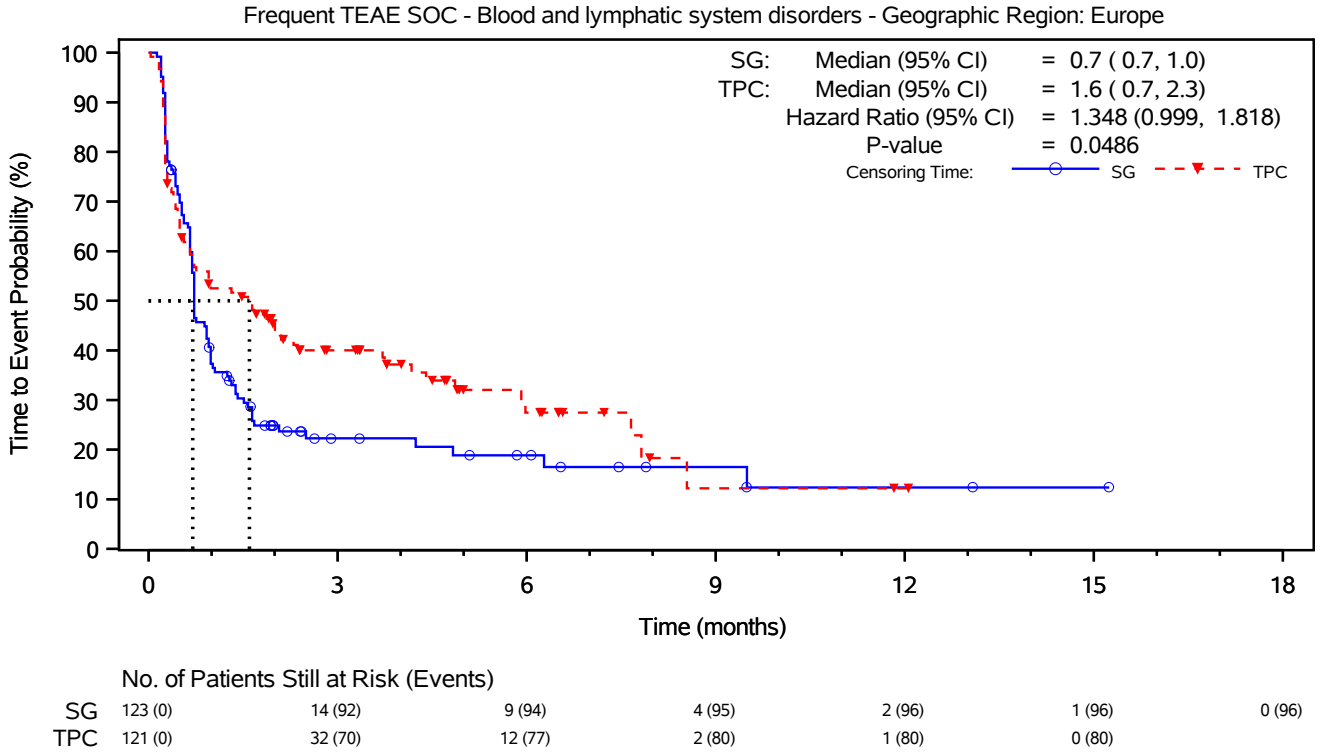
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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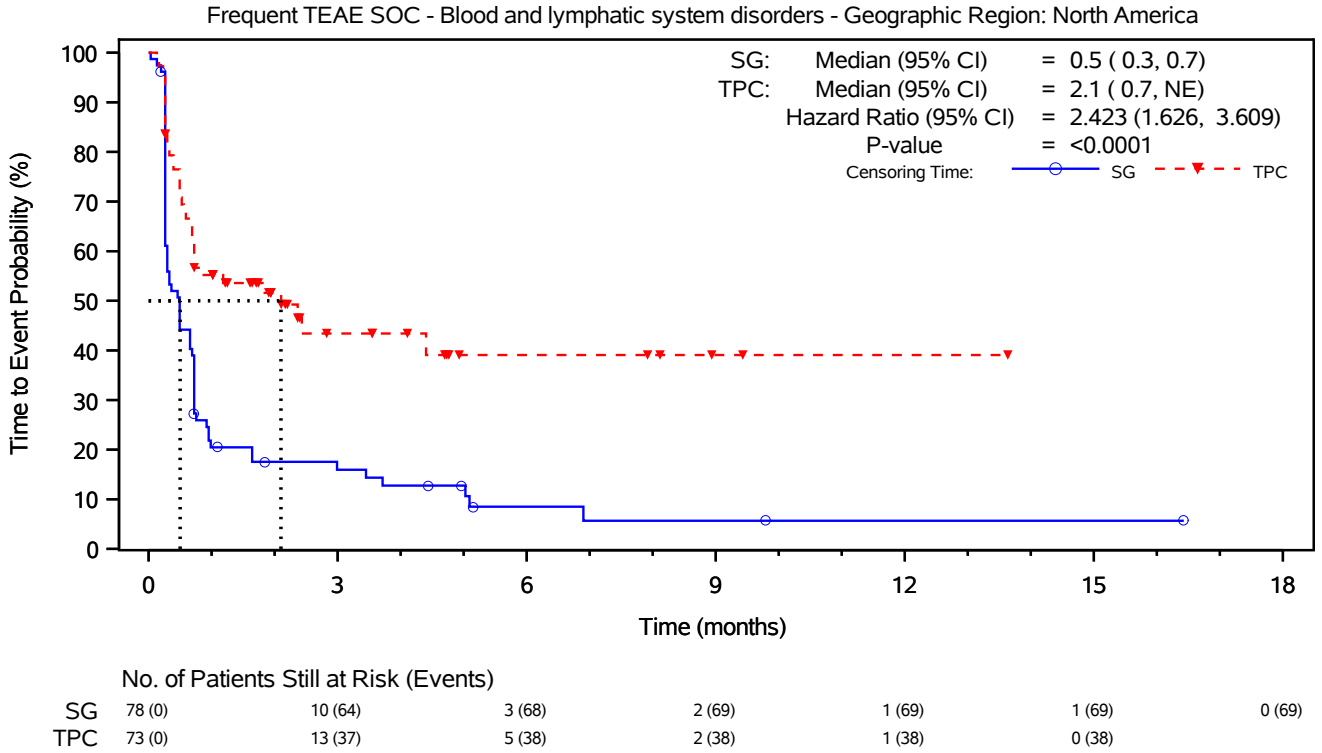
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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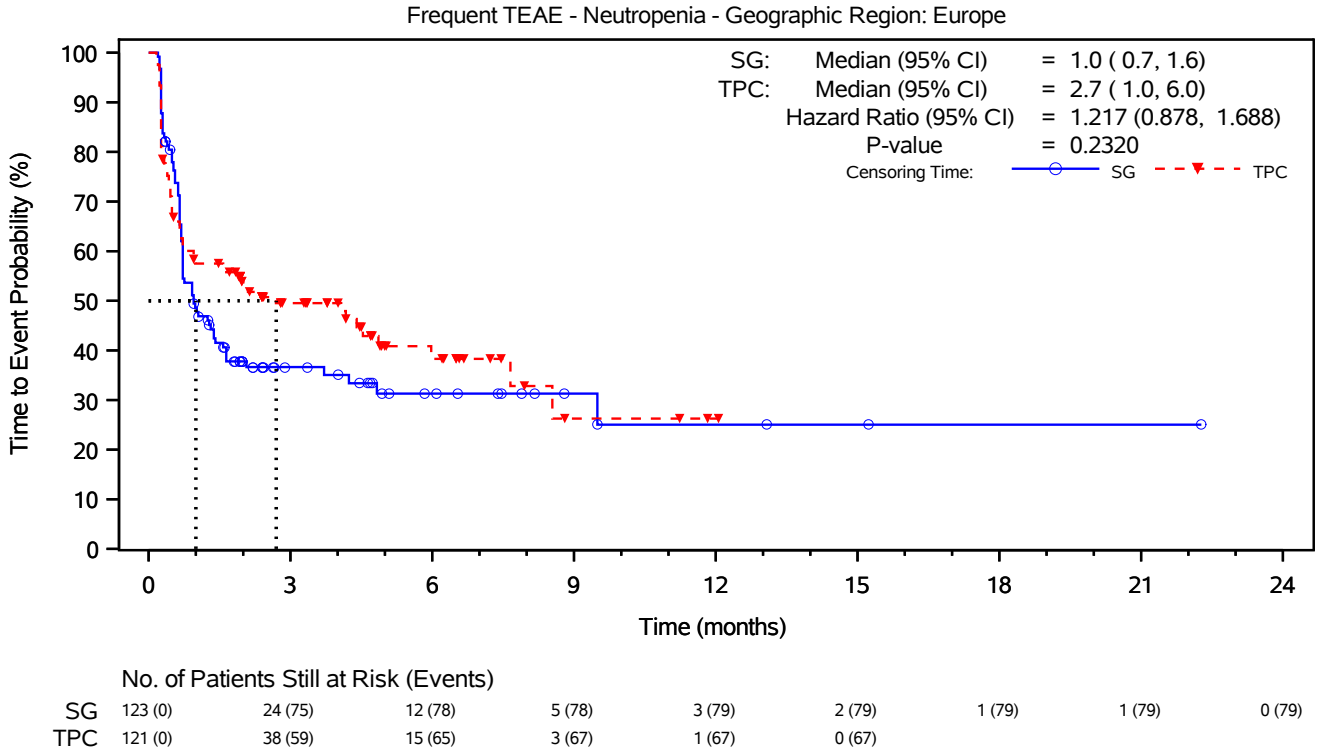
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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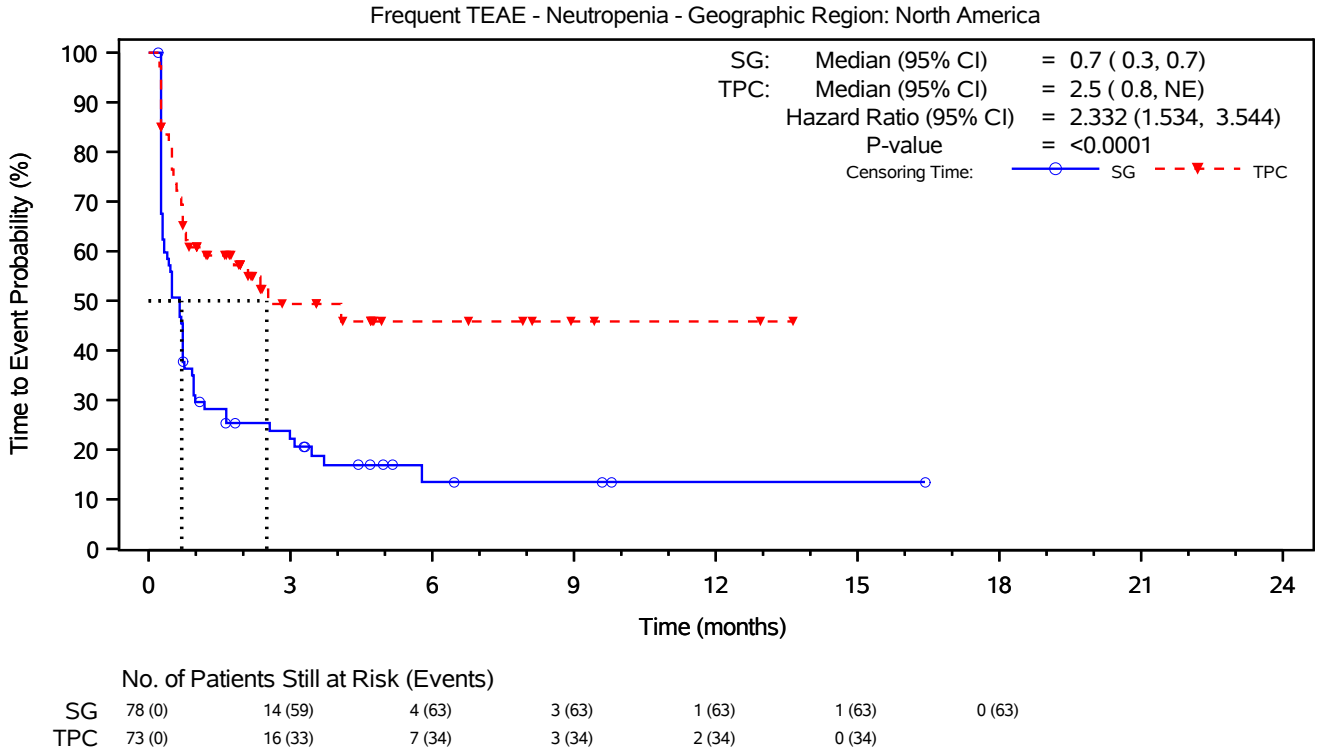
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



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NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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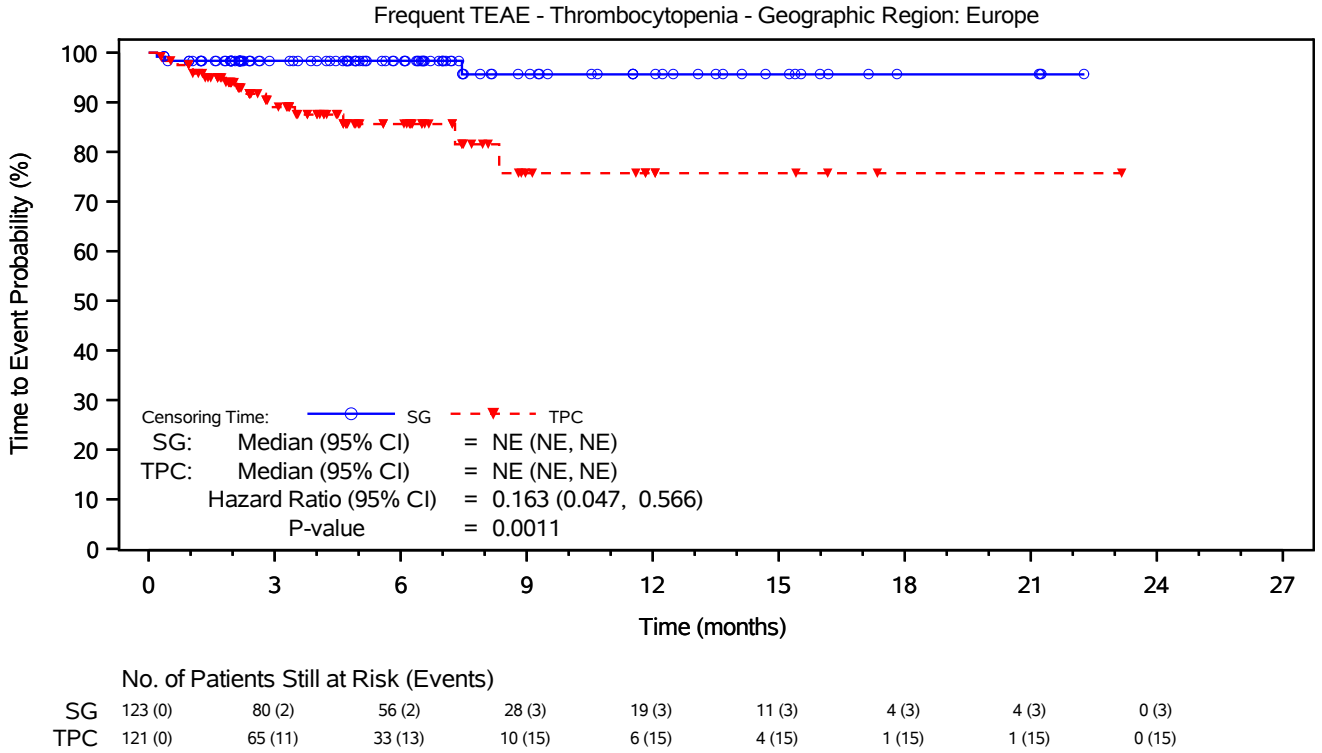
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
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Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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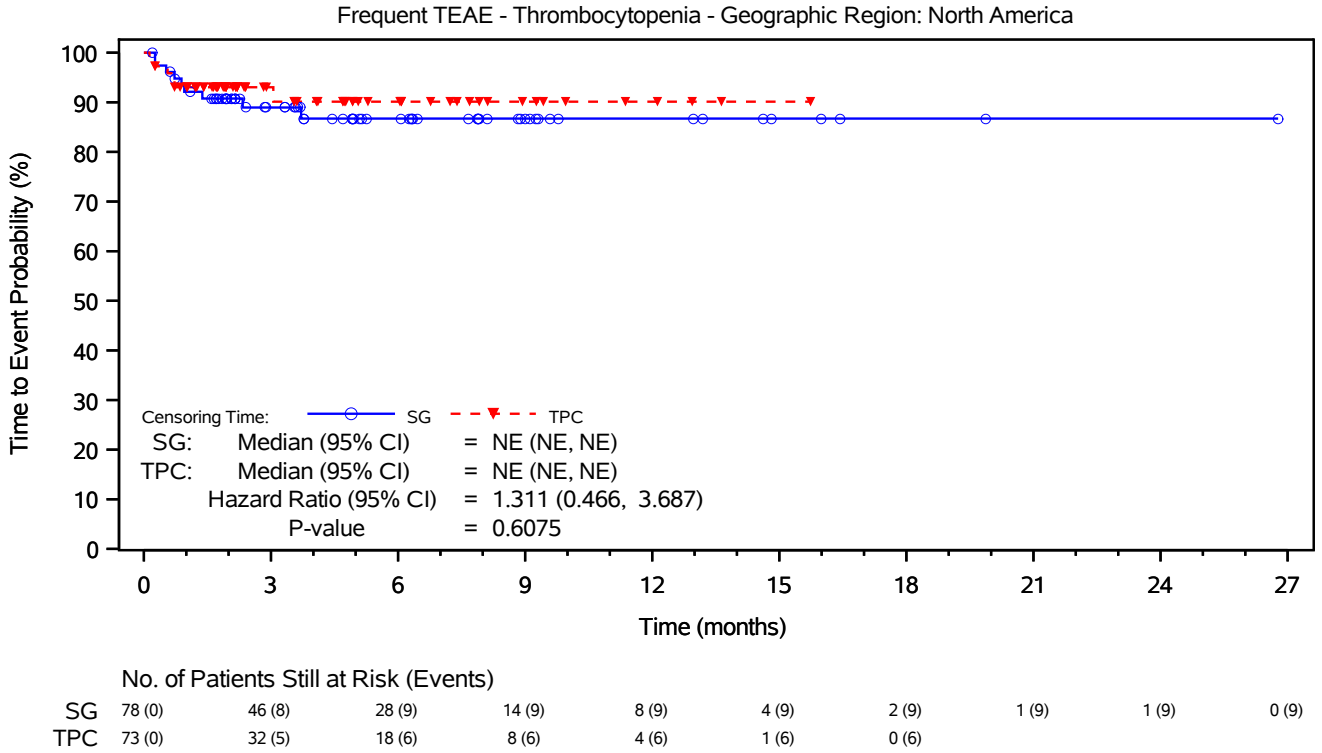
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



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Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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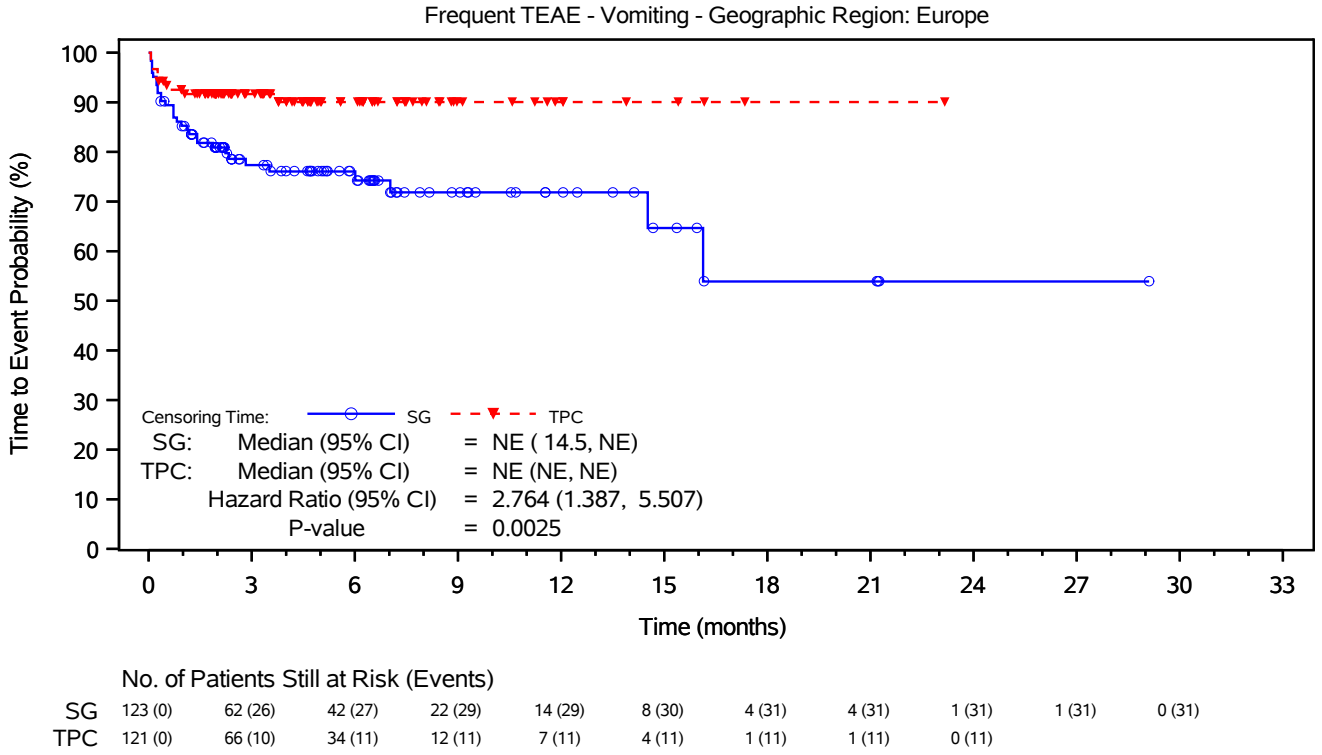
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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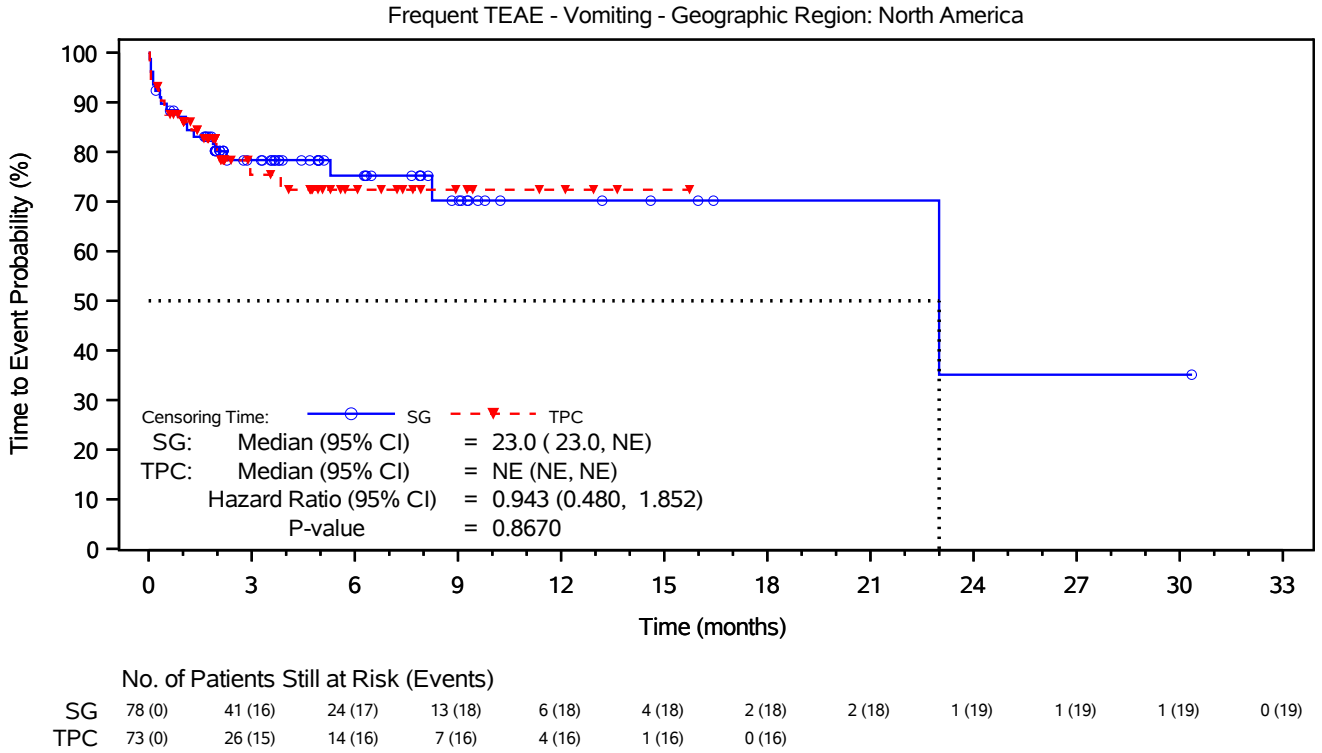
Figure 15.11.7.2.2: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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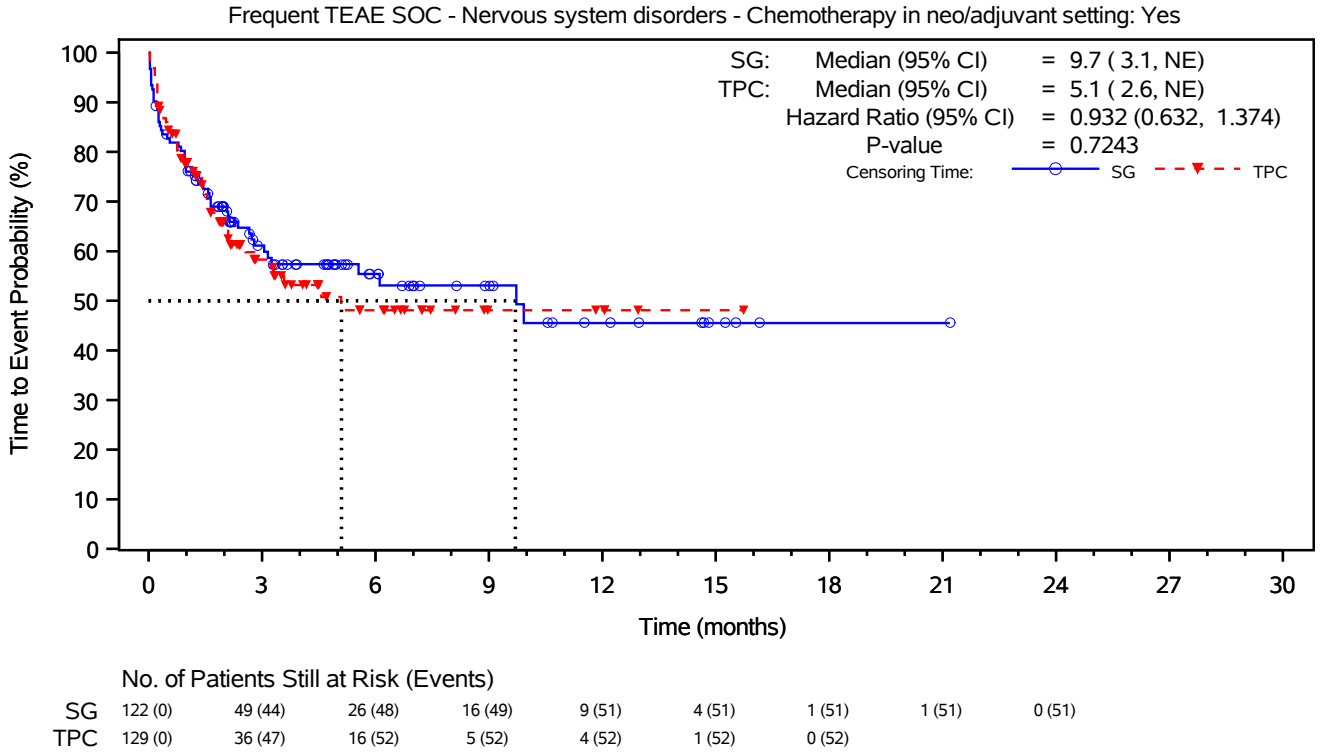
Figure 15.11.7.2.3: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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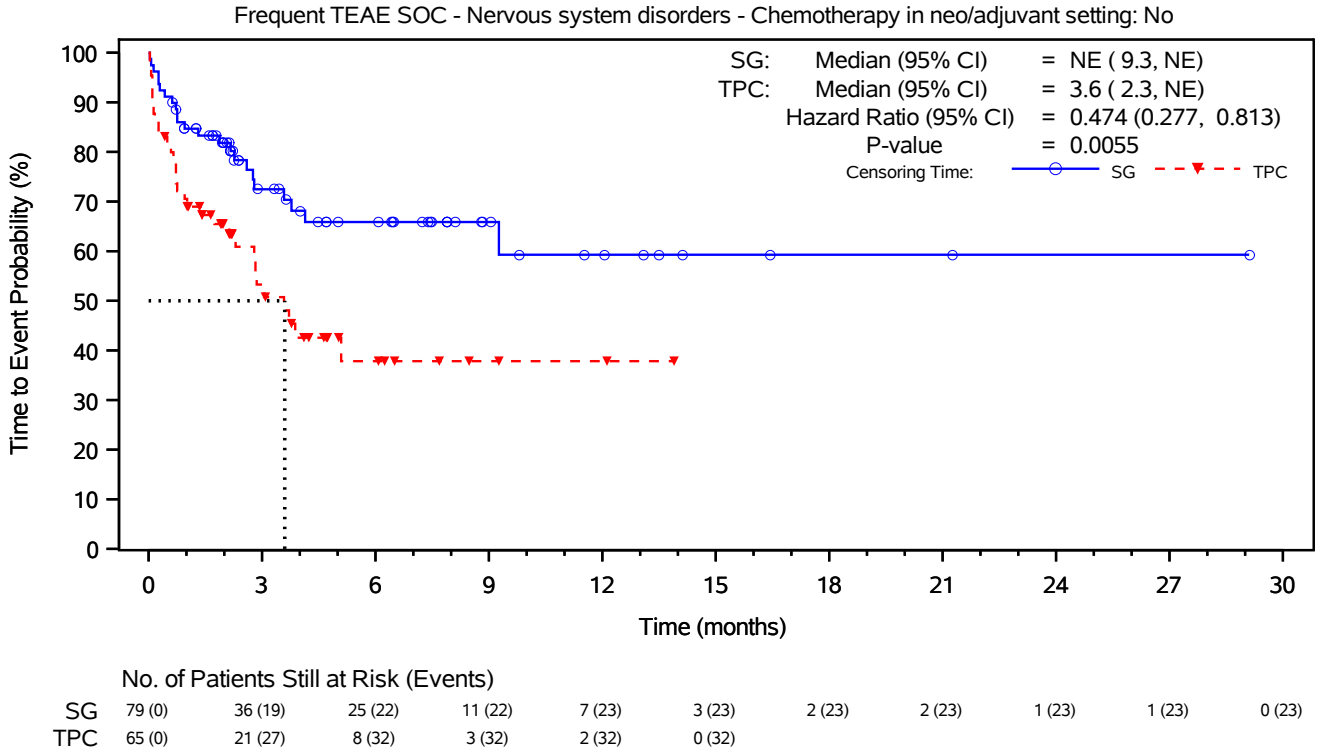
Figure 15.11.7.2.3: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	79 (0)	36 (19)	25 (22)	11 (22)	7 (23)	3 (23)	2 (23)	2 (23)	1 (23)	1 (23)	0 (23)
TPC	65 (0)	21 (27)	8 (32)	3 (32)	2 (32)	0 (32)					

The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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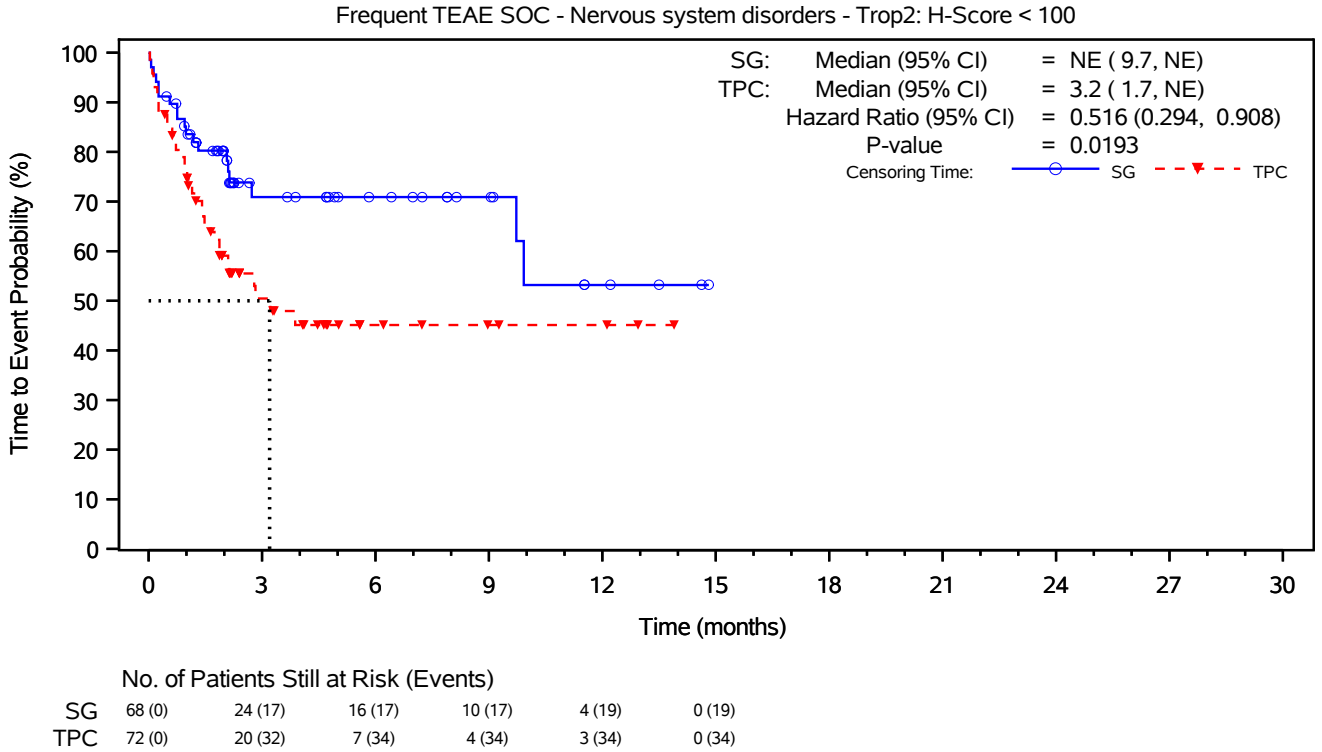
Figure 15.11.7.2.4: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine



No. of Patients Still at Risk (Events)

SG	68 (0)	24 (17)	16 (17)	10 (17)	4 (19)	0 (19)
TPC	72 (0)	20 (32)	7 (34)	4 (34)	3 (34)	0 (34)

The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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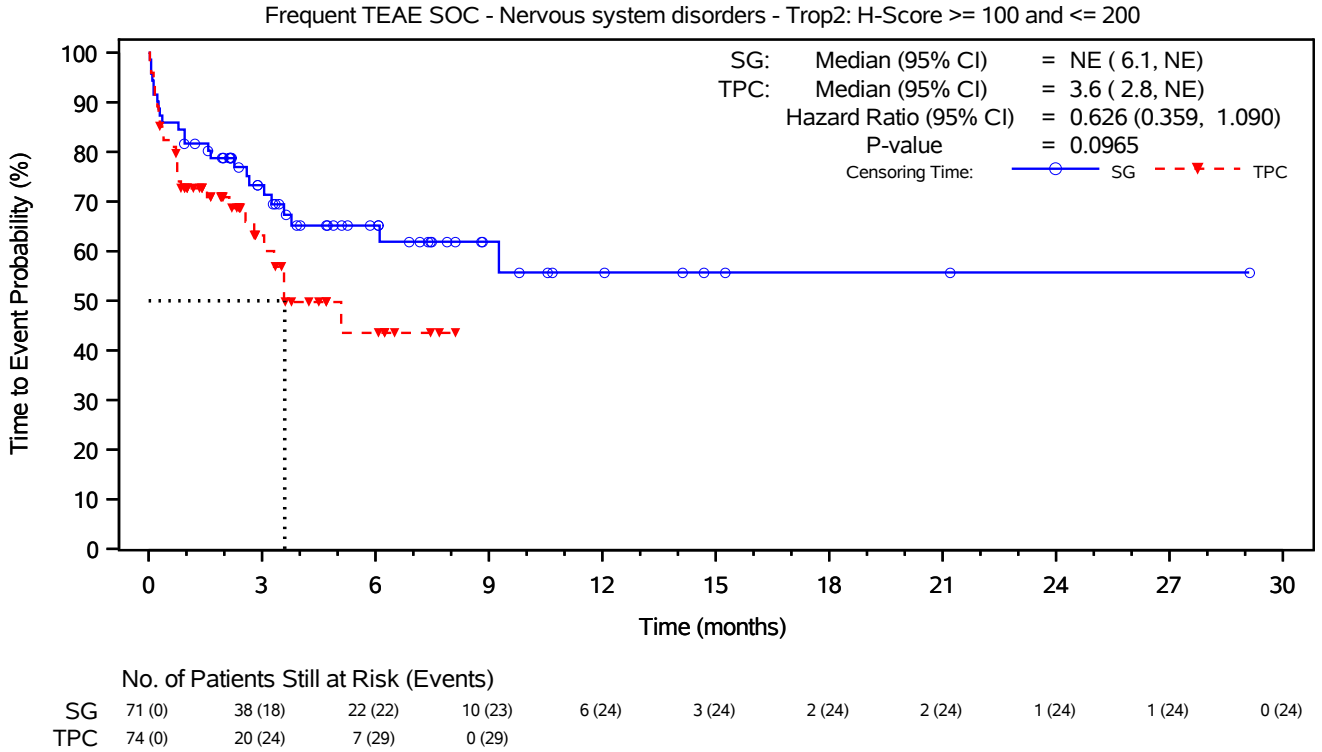
Figure 15.11.7.2.4: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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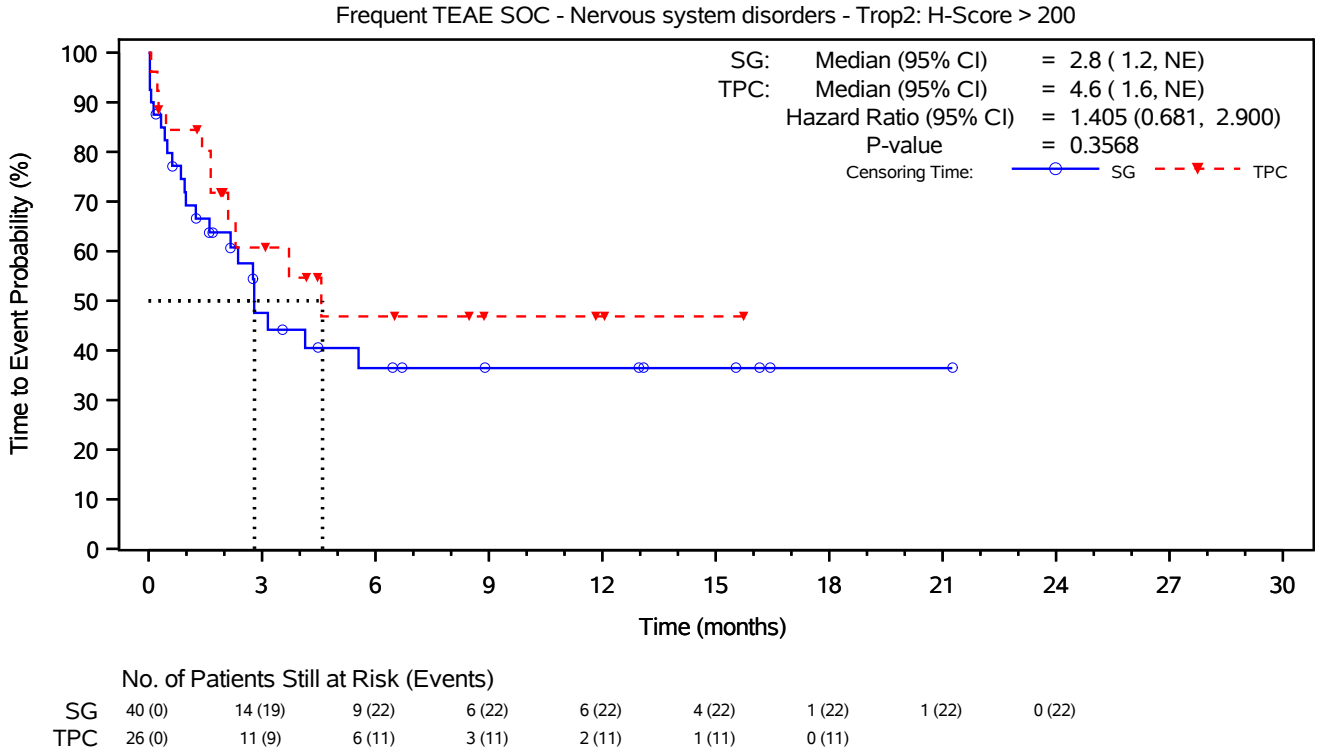
Figure 15.11.7.2.4: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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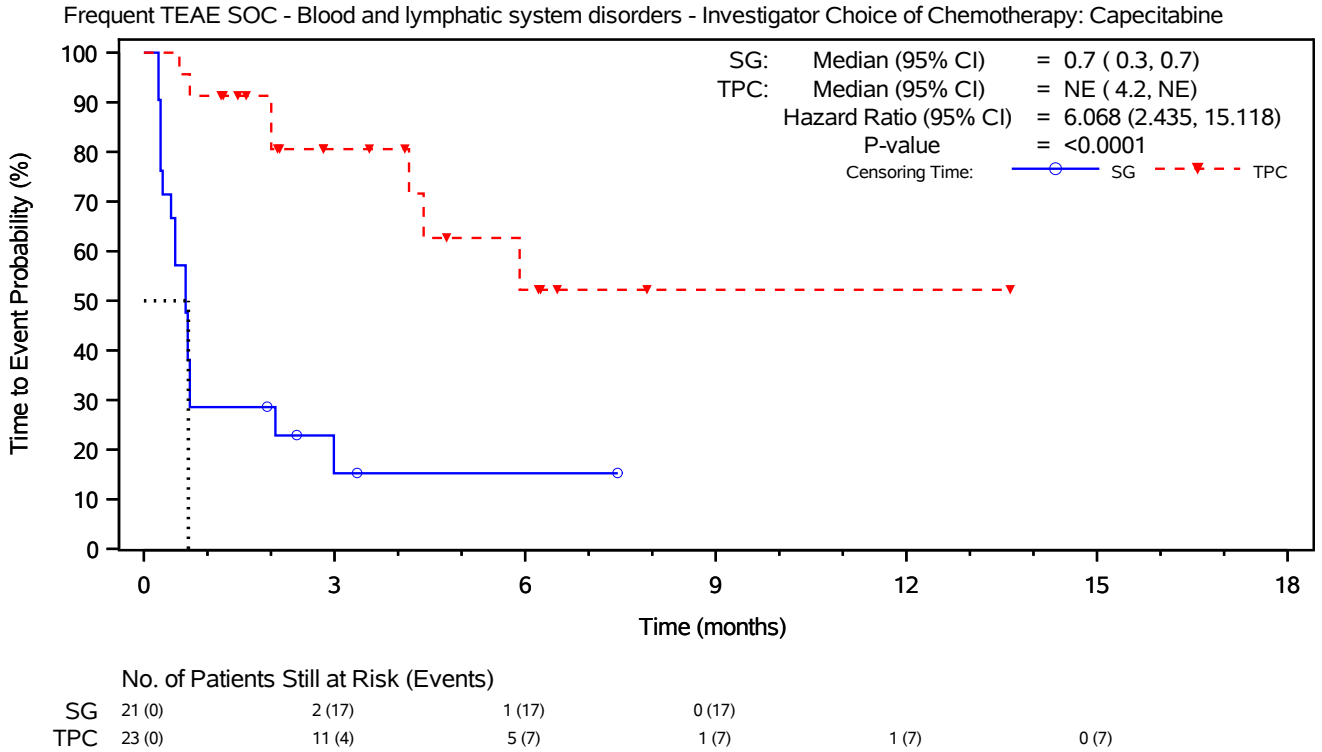
Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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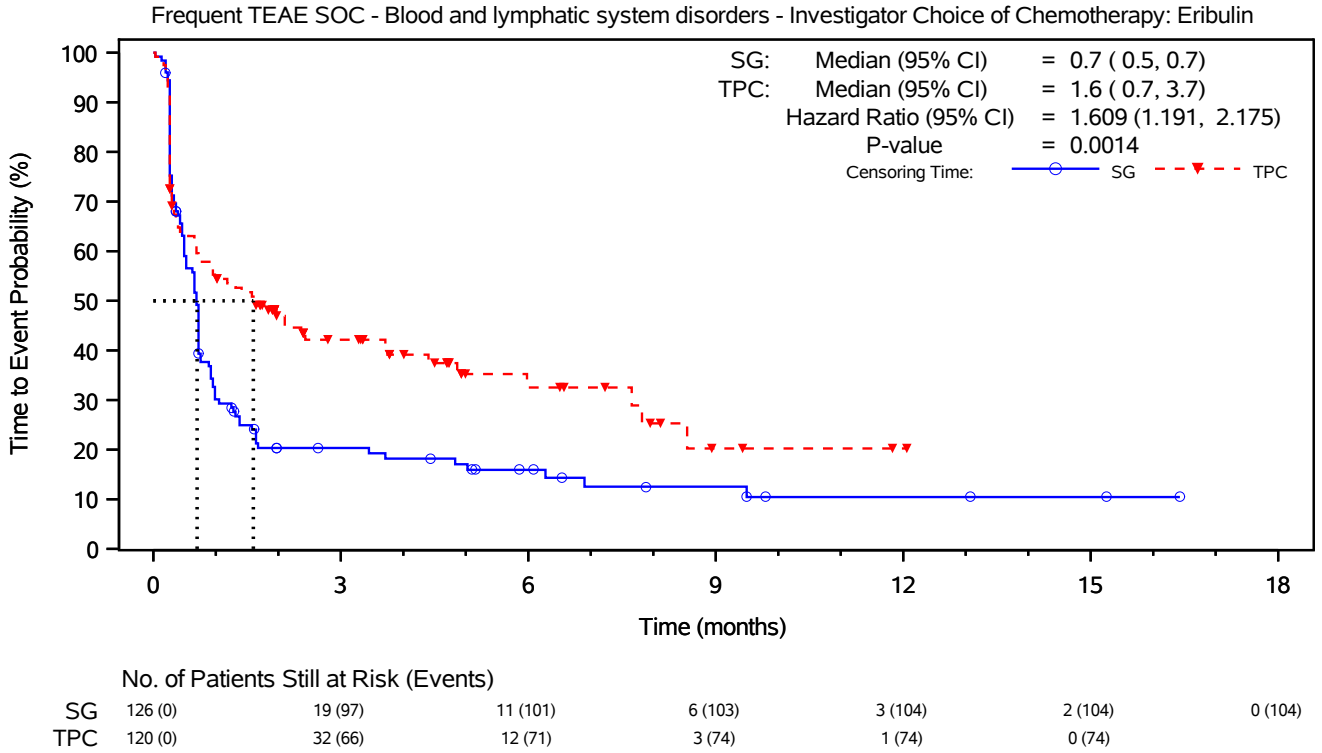
Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
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Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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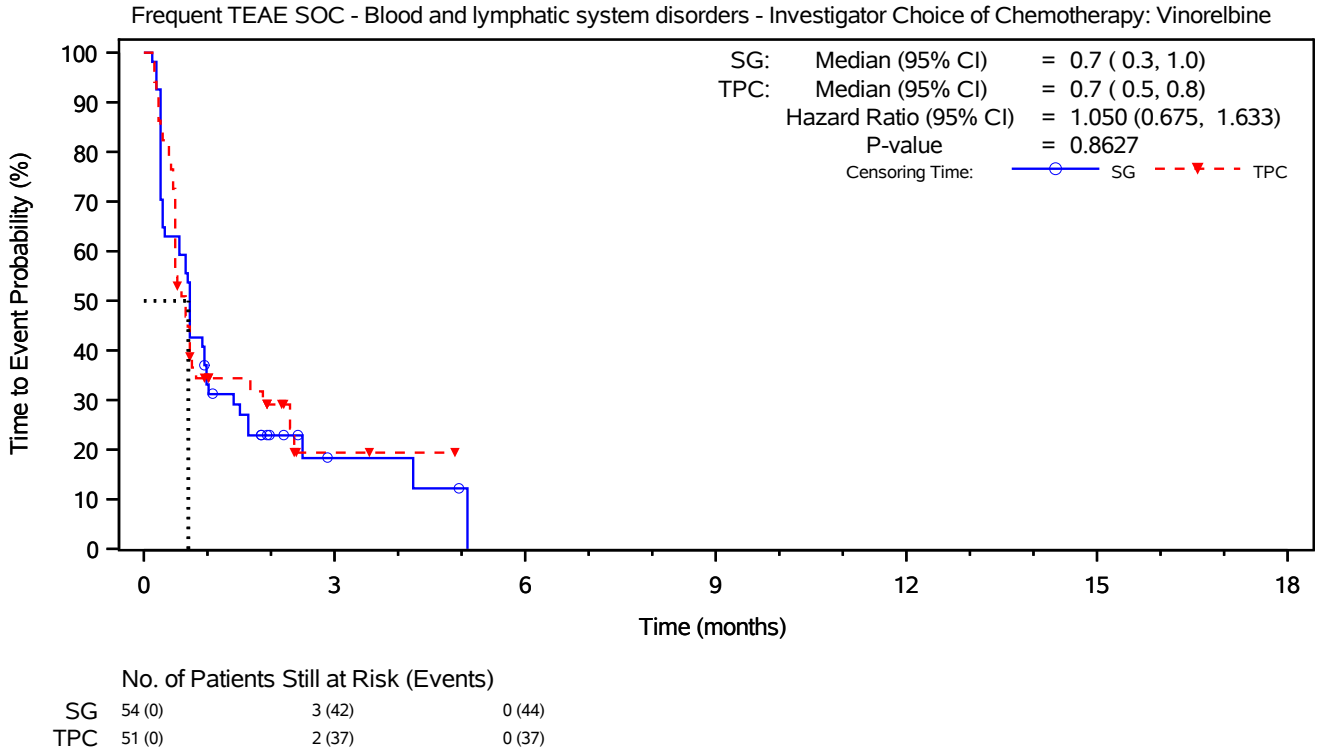
Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

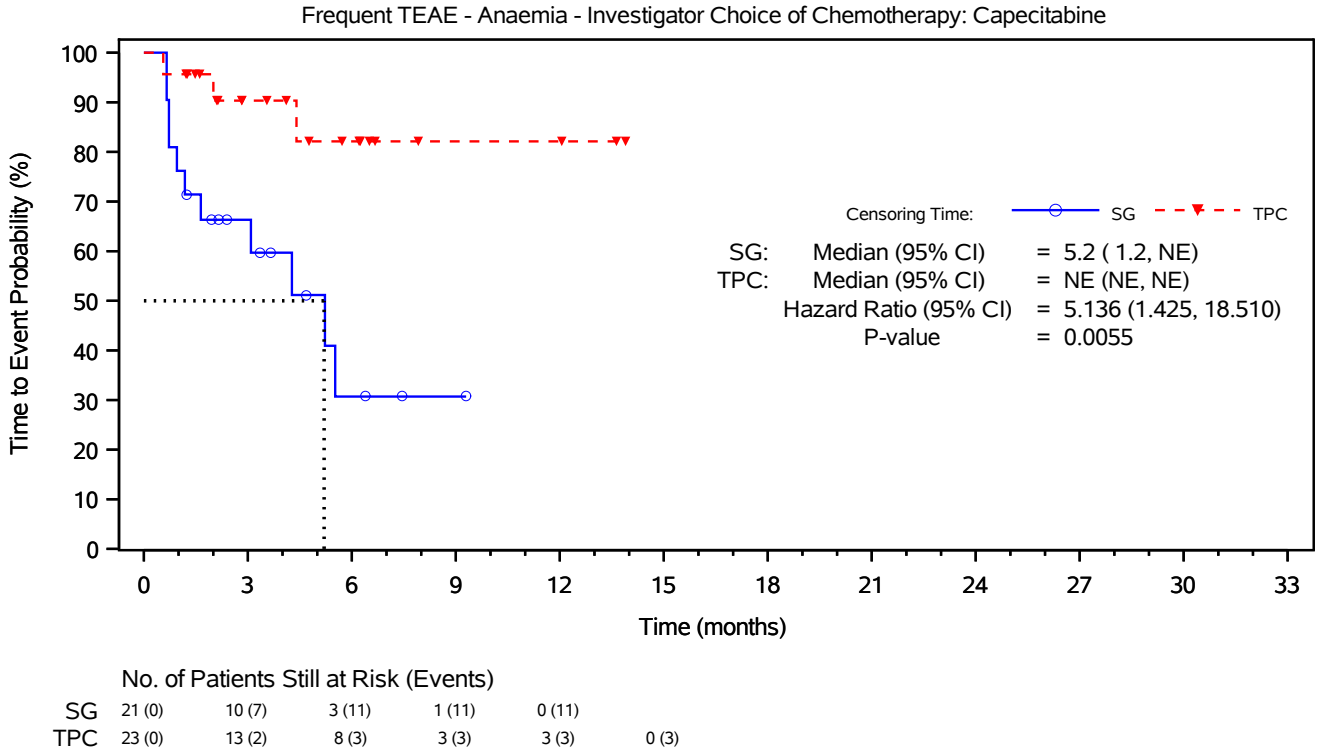

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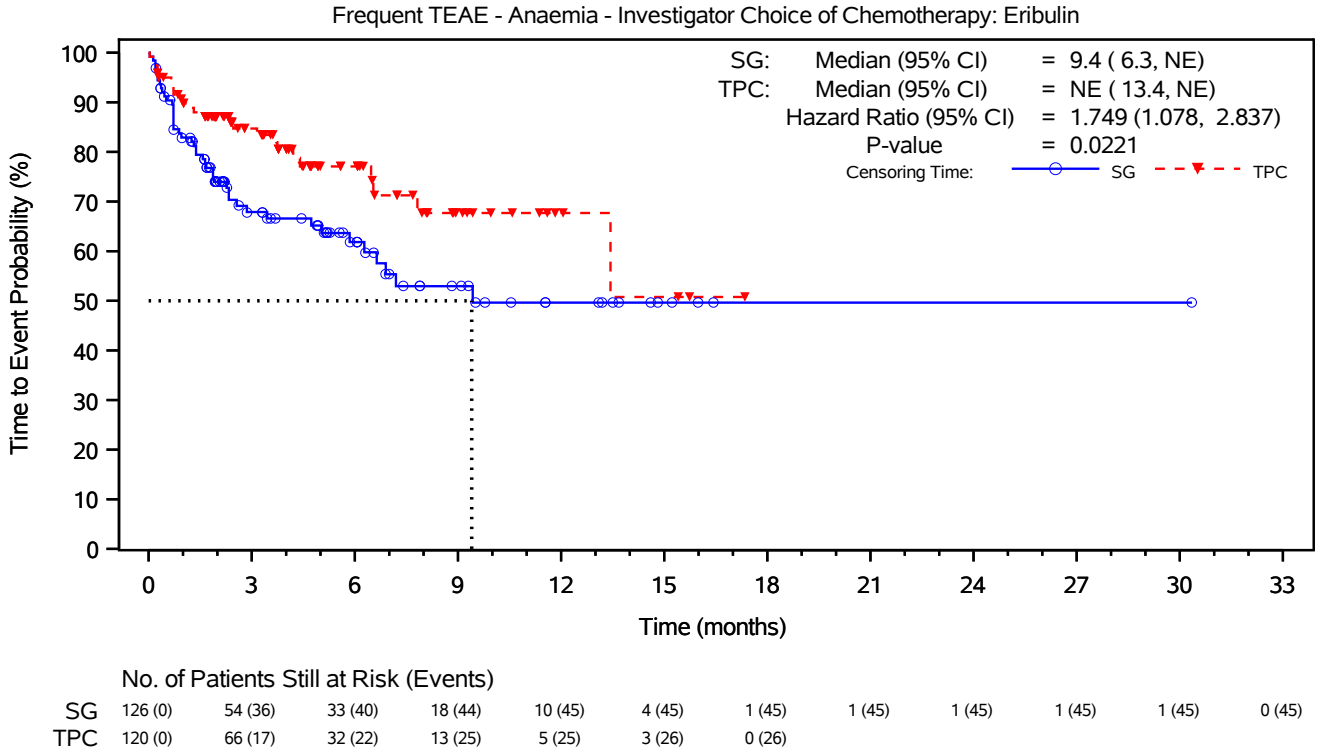
Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



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NE = not estimable.
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Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

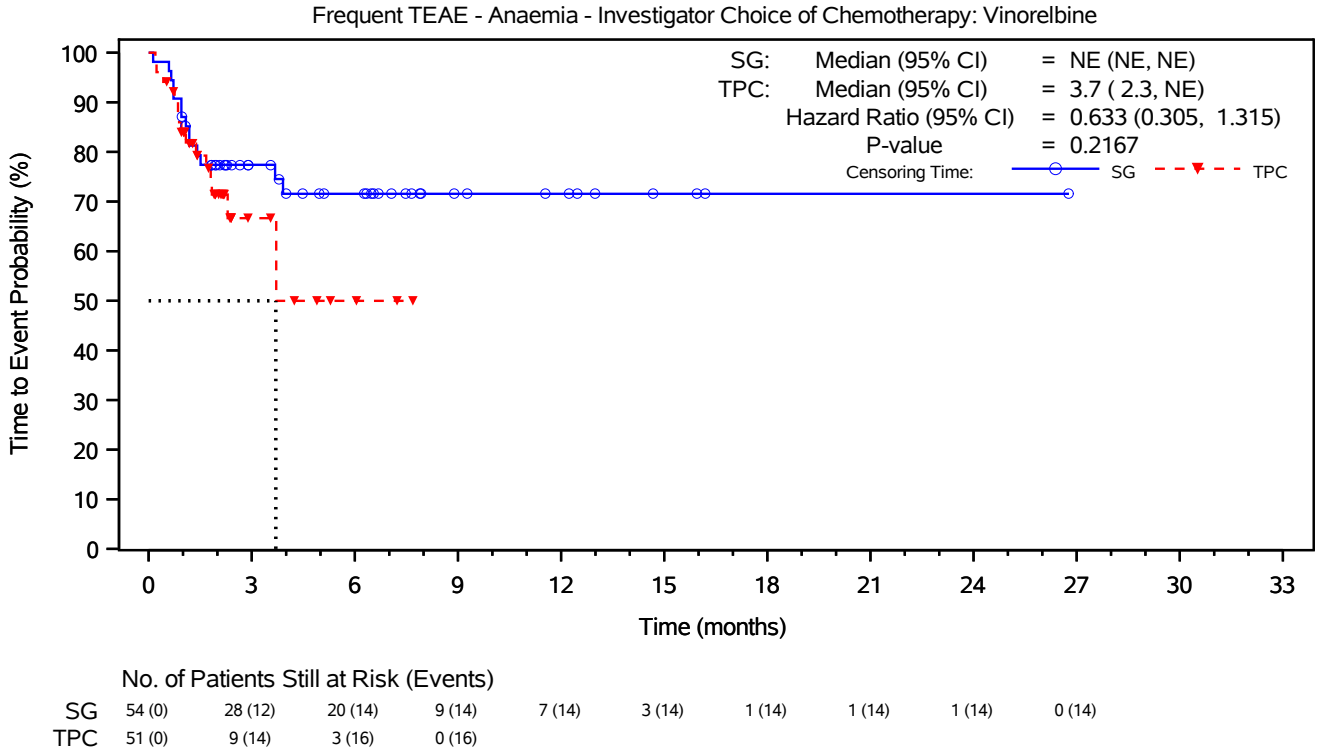

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Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

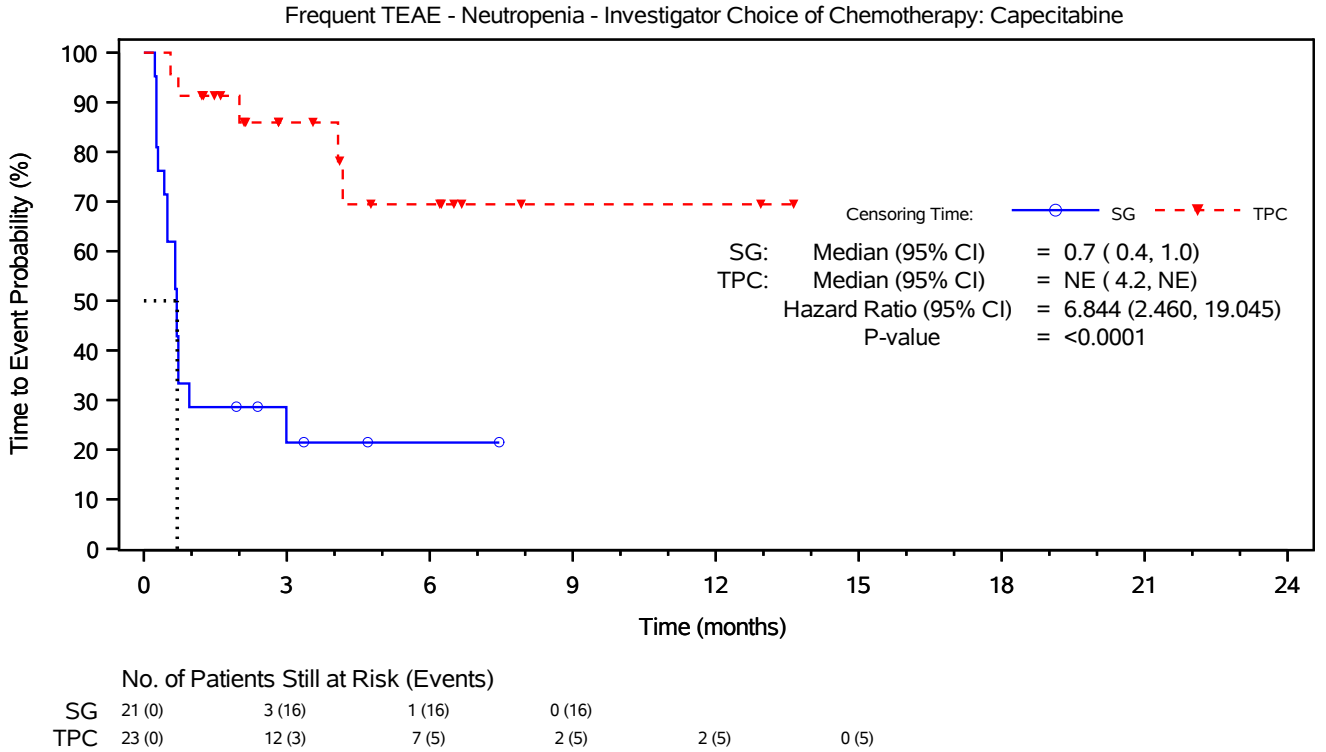

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Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

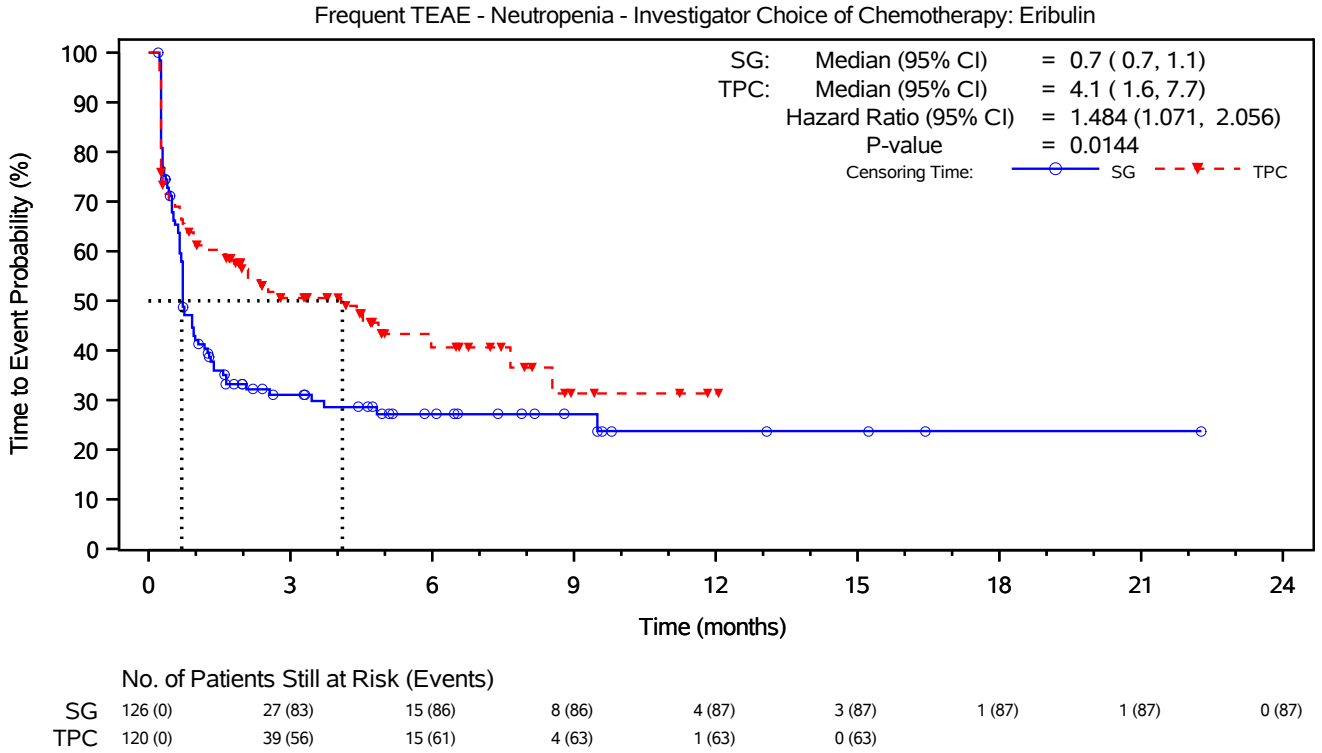

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Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

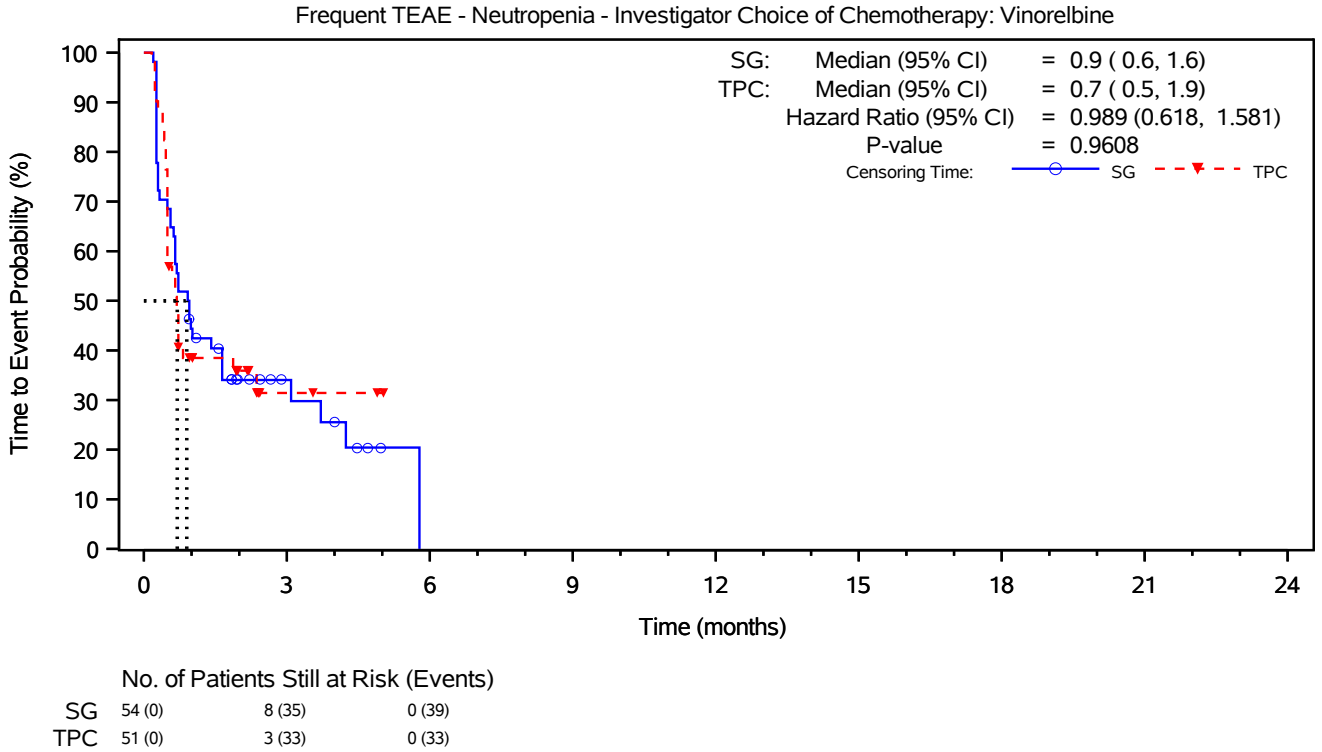

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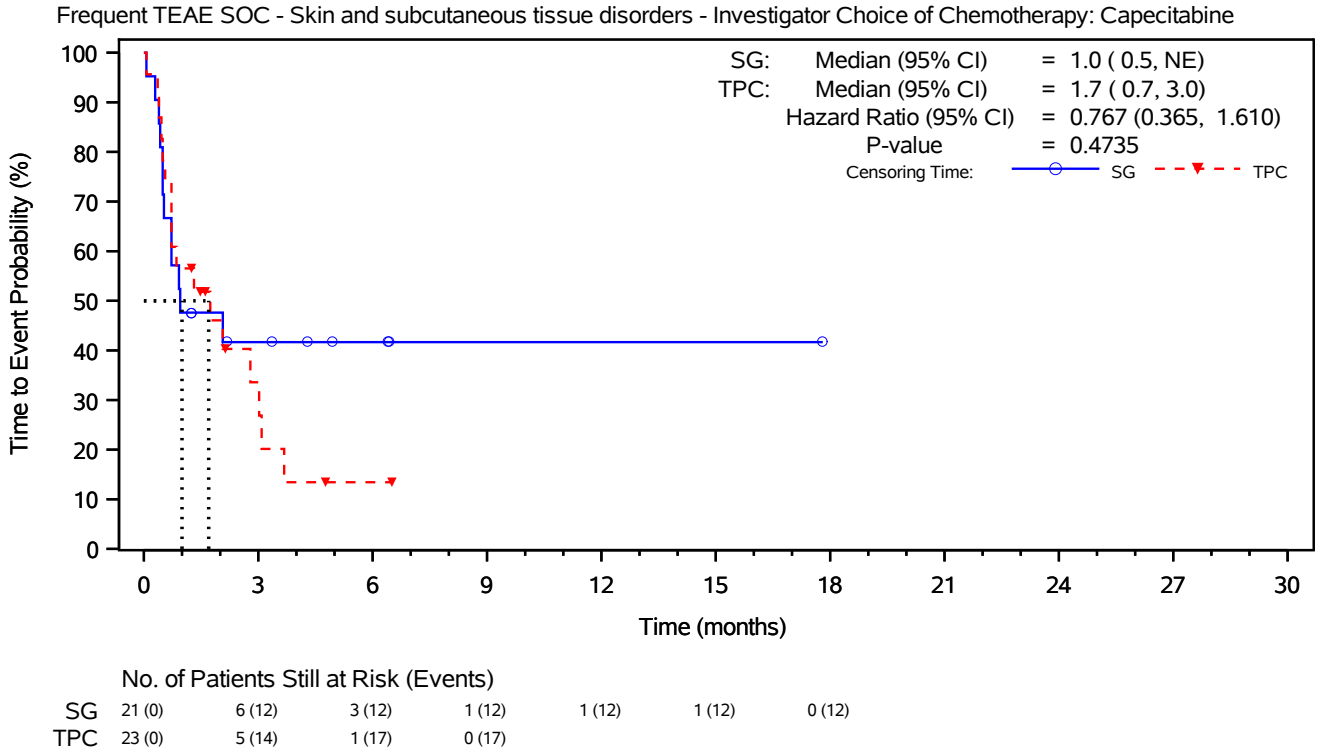
Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



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NE = not estimable.
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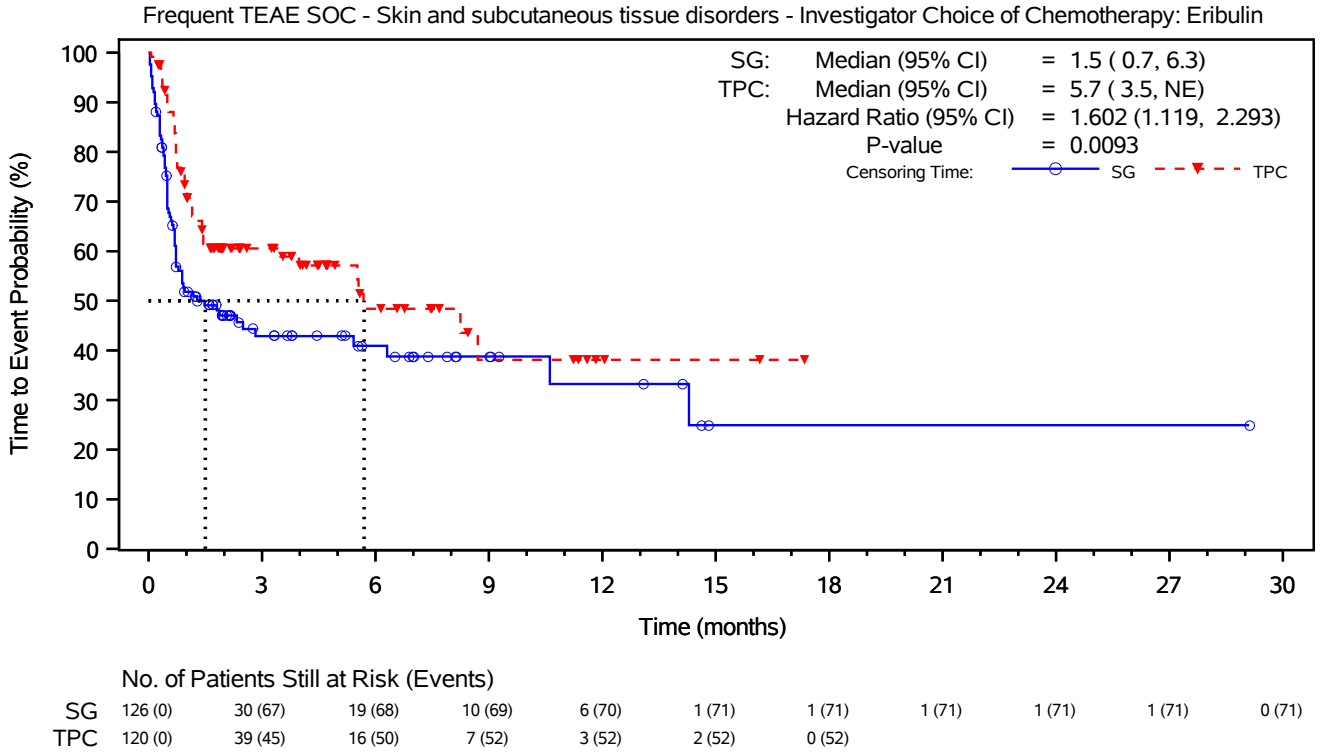
Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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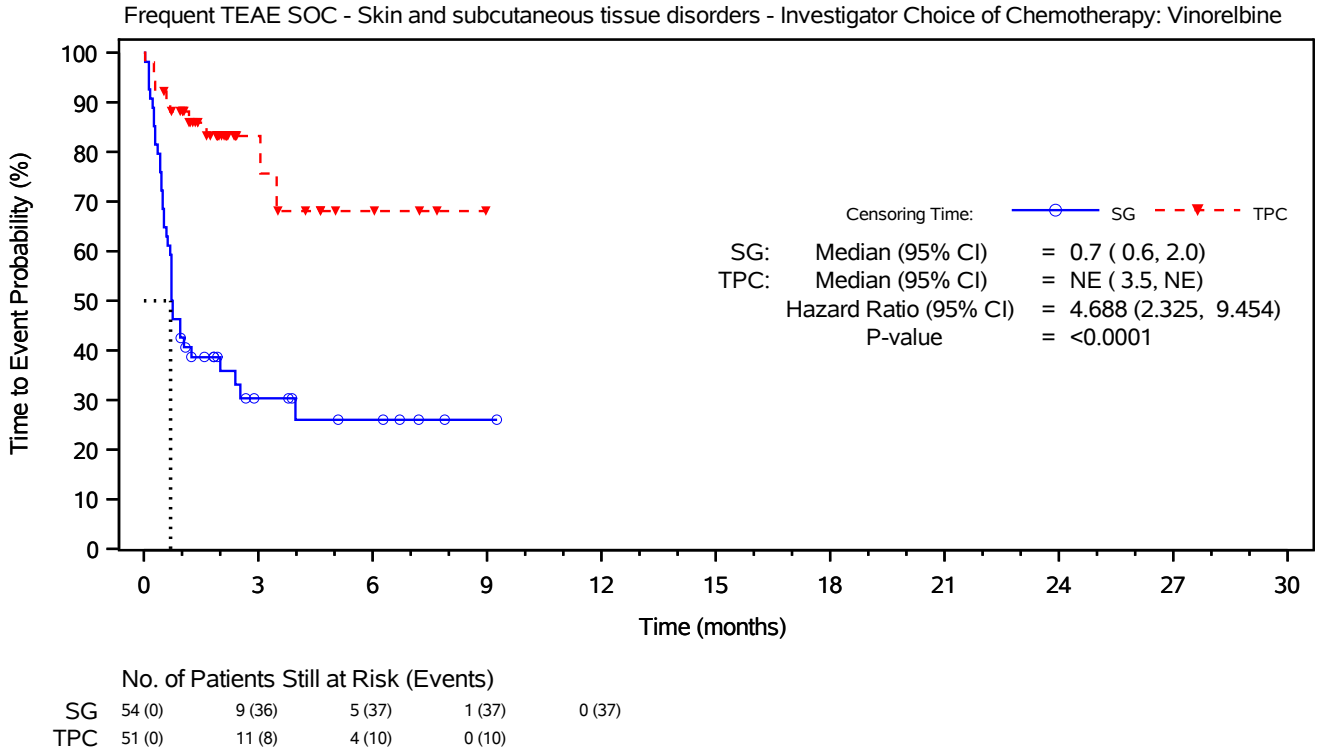
Figure 15.11.7.2.5: KM Plot for Time to the First Frequent TEAE by Selected SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



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Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Table 15.11.7.6.1: Time to the First Frequent Serious TEAE by Selected SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.5290
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	10 (10.5%)	2 (2.2%)	
Patients (%) Without Events (Censored)	85 (89.5%)	90 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.721 (1.034, 21.556)
p-value			0.0273
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	11 (10.4%)	4 (3.9%)	
Patients (%) Without Events (Censored)	95 (89.6%)	98 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.551 (0.811, 8.022)
p-value			0.0969

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.6.2: Time to the First Frequent Serious TEAE by Selected SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9897
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	20 (10.4%)	6 (3.2%)	
Patients (%) Without Events (Censored)	172 (89.6%)	180 (96.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.113 (1.249, 7.758)
p-value			0.0102
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3458

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.6.3: Time to the First Frequent Serious TEAE by Selected SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9878
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	18 (10.0%)	5 (2.9%)	
Patients (%) Without Events (Censored)	162 (90.0%)	166 (97.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.289 (1.220, 8.866)
p-value			0.0127
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	1 (4.3%)	
Patients (%) Without Events (Censored)	18 (85.7%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.443 (0.358, 33.102)
p-value			0.2543

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.6.4: Time to the First Frequent Serious TEAE by Selected SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.8742
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	14 (9.0%)	4 (2.7%)	
Patients (%) Without Events (Censored)	141 (91.0%)	143 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.127 (1.027, 9.514)
p-value			0.0343
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	7 (15.2%)	2 (4.3%)	
Patients (%) Without Events (Censored)	39 (84.8%)	45 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.706 (0.769, 17.856)
p-value			0.0801

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.6.5: Time to the First Frequent Serious TEAE by Selected SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9997
Race: White			
Total Patients	141	132	
Patients (%) With Events	15 (10.6%)	5 (3.8%)	
Patients (%) Without Events (Censored)	126 (89.4%)	127 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.654 (0.963, 7.314)
p-value			0.0498
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.6.6: Time to the First Frequent Serious TEAE by Selected SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.4992
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	7 (8.0%)	3 (3.3%)	
Patients (%) Without Events (Censored)	80 (92.0%)	87 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.442 (0.632, 9.443)
p-value			0.1813
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	14 (12.3%)	3 (2.9%)	
Patients (%) Without Events (Censored)	100 (87.7%)	101 (97.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.123 (1.184, 14.356)
p-value			0.0157

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.7: Time to the First Frequent Serious TEAE by Selected SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9132
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	13 (10.6%)	4 (3.3%)	
Patients (%) Without Events (Censored)	110 (89.4%)	117 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.193 (1.040, 9.801)
p-value			0.0322
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	8 (10.3%)	2 (2.7%)	
Patients (%) Without Events (Censored)	70 (89.7%)	71 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.396 (0.720, 16.012)
p-value			0.1005

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.8: Time to the First Frequent Serious TEAE by Selected SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.7661
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	15 (12.9%)	4 (3.4%)	
Patients (%) Without Events (Censored)	101 (87.1%)	115 (96.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.829 (1.269, 11.554)
p-value			0.0105
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	6 (7.5%)	1 (1.4%)	
Patients (%) Without Events (Censored)	74 (92.5%)	72 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.265 (0.634, 43.719)
p-value			0.0852

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.9: Time to the First Frequent Serious TEAE by Selected SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9994
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	21 (11.6%)	5 (2.8%)	
Patients (%) Without Events (Censored)	160 (88.4%)	171 (97.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.058 (1.529, 10.765)
p-value			0.0023

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.10: Time to the First Frequent Serious TEAE by Selected SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.2730
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	18 (10.2%)	4 (2.3%)	
Patients (%) Without Events (Censored)	159 (89.8%)	167 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.268 (1.444, 12.619)
p-value			0.0043
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	3 (12.5%)	2 (8.7%)	
Patients (%) Without Events (Censored)	21 (87.5%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.204 (0.200, 7.256)
p-value			0.8392

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.11: Time to the First Frequent Serious TEAE by Selected SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.5710
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	14 (11.5%)	5 (3.9%)	
Patients (%) Without Events (Censored)	108 (88.5%)	124 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.880 (1.037, 8.003)
p-value			0.0338
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	7 (8.9%)	1 (1.5%)	
Patients (%) Without Events (Censored)	72 (91.1%)	64 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.507 (0.676, 44.846)
p-value			0.0730

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.12: Time to the First Frequent Serious TEAE by Selected SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.8203
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	10 (14.7%)	4 (5.6%)	
Patients (%) Without Events (Censored)	58 (85.3%)	68 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.833 (0.888, 9.036)
p-value			0.0666
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	7 (9.9%)	0	
Patients (%) Without Events (Censored)	64 (90.1%)	74 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0137
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.12: Time to the First Frequent Serious TEAE by Selected SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (7.5%)	1 (3.8%)	
Patients (%) Without Events (Censored)	37 (92.5%)	25 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.016 (0.210, 19.388)
p-value			0.5357

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

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Table 15.11.7.6.13: Time to the First Frequent Serious TEAE by Selected SOC,PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TESAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9894
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	3 (13.0%)	
Patients (%) Without Events (Censored)	18 (85.7%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.097 (0.221, 5.437)
p-value			0.9096
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	13 (10.3%)	3 (2.5%)	
Patients (%) Without Events (Censored)	113 (89.7%)	117 (97.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.315 (1.230, 15.144)
p-value			0.0128
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.6.13: Time to the First Frequent Serious TEAE by Selected SOC,PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	5 (9.3%)	0	
Patients (%) Without Events (Censored)	49 (90.7%)	51 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0611

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
NE = not estimable. The SOC/PT is kept if the stratified log-rank test for treatment comparison is significant.
Treatment-emergent adverse events are defined as any AEs that started on or after the first dose date and up to 30 days after the last dose date.
The following terms are mapped: Neutrophil count decreased->Neutropenia, White blood cell count decreased->Leukopenia, Lymphocyte count decreased ->Lymphopenia, Haemoglobin decreased->Anaemia, Red blood cell count decreased->Anaemia, Platelet count decreased->Thrombocytopenia
The analysis is based on Interim 2 data cut at 7/1/2022.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.1: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.0539
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	58 (61.1%)	33 (35.9%)	
Patients (%) Without Events (Censored)	37 (38.9%)	59 (64.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.7, 3.0)	NE (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.964 (1.280, 3.015)
p-value			0.0014
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	57 (53.8%)	50 (49.0%)	
Patients (%) Without Events (Censored)	49 (46.2%)	52 (51.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (1.0, NE)	2.8 (1.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.119 (0.765, 1.637)
p-value			0.5848

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.1: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.1491
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	4 (4.2%)	3 (3.3%)	
Patients (%) Without Events (Censored)	91 (95.8%)	89 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.132 (0.253, 5.070)
p-value			0.8714
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	12 (11.3%)	2 (2.0%)	
Patients (%) Without Events (Censored)	94 (88.7%)	100 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.434 (1.214, 24.319)
p-value			0.0130

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.1: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.0436
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	52 (54.7%)	28 (30.4%)	
Patients (%) Without Events (Censored)	43 (45.3%)	64 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (0.9, NE)	NE (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.002 (1.263, 3.171)
p-value			0.0023
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	52 (49.1%)	47 (46.1%)	
Patients (%) Without Events (Censored)	54 (50.9%)	55 (53.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	4.6 (1.0, NE)	8.3 (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.077 (0.726, 1.599)
p-value			0.7423

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.1: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.3786
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	12 (12.6%)	6 (6.5%)	
Patients (%) Without Events (Censored)	83 (87.4%)	86 (93.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.860 (0.697, 4.964)
p-value			0.2095
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	19 (17.9%)	5 (4.9%)	
Patients (%) Without Events (Censored)	87 (82.1%)	97 (95.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.551 (1.325, 9.521)
p-value			0.0072

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.1: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.7656
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	8 (8.4%)	1 (1.1%)	
Patients (%) Without Events (Censored)	87 (91.6%)	91 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.548 (0.942, 60.448)
p-value			0.0250
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	11 (10.4%)	2 (2.0%)	
Patients (%) Without Events (Censored)	95 (89.6%)	100 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.188 (1.150, 23.412)
p-value			0.0168

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.1: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.3350
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	2 (2.1%)	8 (8.7%)	
Patients (%) Without Events (Censored)	93 (97.9%)	84 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.180 (0.038, 0.852)
p-value			0.0151
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	5 (4.7%)	6 (5.9%)	
Patients (%) Without Events (Censored)	101 (95.3%)	96 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.542 (0.152, 1.930)
p-value			0.3373

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.1: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.8128
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 2			
Total Patients	95	92	
Patients (%) With Events	5 (5.3%)	7 (7.6%)	
Patients (%) Without Events (Censored)	90 (94.7%)	85 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.547 (0.172, 1.737)
p-value			0.2994
Stratification factor of prior chemotherapy regimens for treatment of metastatic disease: 3-4			
Total Patients	106	102	
Patients (%) With Events	6 (5.7%)	10 (9.8%)	
Patients (%) Without Events (Censored)	100 (94.3%)	92 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.484 (0.175, 1.339)
p-value			0.1534

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.2: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.9289
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	110 (57.3%)	79 (42.5%)	
Patients (%) Without Events (Censored)	82 (42.7%)	107 (57.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (1.0, 3.0)	8.3 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.463 (1.096, 1.955)
p-value			0.0096
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	5 (55.6%)	4 (50.0%)	
Patients (%) Without Events (Censored)	4 (44.4%)	4 (50.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, NE)	NE (0.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.618 (0.431, 6.067)
p-value			0.4805

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.2: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.9997
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	16 (8.3%)	5 (2.7%)	
Patients (%) Without Events (Censored)	176 (91.7%)	181 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.859 (1.046, 7.815)
p-value			0.0323
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.2: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.6611
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	99 (51.6%)	72 (38.7%)	
Patients (%) Without Events (Censored)	93 (48.4%)	114 (61.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (1.1, NE)	9.6 (4.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.407 (1.038, 1.906)
p-value			0.0278
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	5 (55.6%)	3 (37.5%)	
Patients (%) Without Events (Censored)	4 (44.4%)	5 (62.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.6 (0.3, NE)	NE (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.279 (0.538, 9.644)
p-value			0.2553

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.2: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9872
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	30 (15.6%)	11 (5.9%)	
Patients (%) Without Events (Censored)	162 (84.4%)	175 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.541 (1.272, 5.076)
p-value			0.0063
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3458

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.2: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9994
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	19 (9.9%)	3 (1.6%)	
Patients (%) Without Events (Censored)	173 (90.1%)	183 (98.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.974 (1.766, 20.210)
p-value			0.0011
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	9 (100.0%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.2: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.9899
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	6 (3.1%)	14 (7.5%)	
Patients (%) Without Events (Censored)	186 (96.9%)	172 (92.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.272 (0.097, 0.759)
p-value			0.0078
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.5, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.4142

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.2: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Visceral Metastasis
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.9880
Stratification factor of visceral metastasis: Yes			
Total Patients	192	186	
Patients (%) With Events	10 (5.2%)	17 (9.1%)	
Patients (%) Without Events (Censored)	182 (94.8%)	169 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.468 (0.213, 1.027)
p-value			0.0529
Stratification factor of visceral metastasis: No			
Total Patients	9	8	
Patients (%) With Events	1 (11.1%)	0	
Patients (%) Without Events (Censored)	8 (88.9%)	8 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.4795

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.1319
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	107 (59.4%)	72 (42.1%)	
Patients (%) Without Events (Censored)	73 (40.6%)	99 (57.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.9, 3.0)	8.3 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.570 (1.164, 2.117)
p-value			0.0030
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	8 (38.1%)	11 (47.8%)	
Patients (%) Without Events (Censored)	13 (61.9%)	12 (52.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.6, NE)	2.4 (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.727 (0.291, 1.817)
p-value			0.4926

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.7990
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	14 (7.8%)	4 (2.3%)	
Patients (%) Without Events (Censored)	166 (92.2%)	167 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.052 (1.003, 9.287)
p-value			0.0386
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	1 (4.3%)	
Patients (%) Without Events (Censored)	19 (90.5%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.896 (0.171, 21.039)
p-value			0.5963

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.1335
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	98 (54.4%)	66 (38.6%)	
Patients (%) Without Events (Censored)	82 (45.6%)	105 (61.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (1.0, 6.9)	9.6 (4.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.534 (1.123, 2.097)
p-value			0.0072
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	6 (28.6%)	9 (39.1%)	
Patients (%) Without Events (Censored)	15 (71.4%)	14 (60.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	4.3 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.669 (0.237, 1.888)
p-value			0.4426

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9501
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	26 (14.4%)	9 (5.3%)	
Patients (%) Without Events (Censored)	154 (85.6%)	162 (94.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.620 (1.226, 5.600)
p-value			0.0099
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	5 (23.8%)	2 (8.7%)	
Patients (%) Without Events (Censored)	16 (76.2%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.738 (0.530, 14.131)
p-value			0.2099

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9909
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	16 (8.9%)	3 (1.8%)	
Patients (%) Without Events (Censored)	164 (91.1%)	168 (98.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.860 (1.414, 16.707)
p-value			0.0055
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	3 (14.3%)	0	
Patients (%) Without Events (Censored)	18 (85.7%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0738

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.9905
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	6 (3.3%)	14 (8.2%)	
Patients (%) Without Events (Censored)	174 (96.7%)	157 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.257 (0.092, 0.720)
p-value			0.0054
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	0	
Patients (%) Without Events (Censored)	20 (95.2%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2953

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.3: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Endocrin Therapy in the Metastatic Setting for >=6 Months
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.4558
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: Yes			
Total Patients	180	171	
Patients (%) With Events	9 (5.0%)	15 (8.8%)	
Patients (%) Without Events (Censored)	171 (95.0%)	156 (91.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.457 (0.199, 1.051)
p-value			0.0592
Stratification factor of endocrine therapy in the metastatic setting for >=6 months: No			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	2 (8.7%)	
Patients (%) Without Events (Censored)	19 (90.5%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.823 (0.112, 6.044)
p-value			0.8475

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.4: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.7397
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	89 (57.4%)	63 (42.9%)	
Patients (%) Without Events (Censored)	66 (42.6%)	84 (57.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.4 (0.9, 3.7)	8.3 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.416 (1.025, 1.956)
p-value			0.0351
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	26 (56.5%)	20 (42.6%)	
Patients (%) Without Events (Censored)	20 (43.5%)	27 (57.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, NE)	6.0 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.584 (0.882, 2.842)
p-value			0.1238

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.4: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.3807
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	10 (6.5%)	4 (2.7%)	
Patients (%) Without Events (Censored)	145 (93.5%)	143 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.101 (0.656, 6.721)
p-value			0.2007
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	6 (13.0%)	1 (2.1%)	
Patients (%) Without Events (Censored)	40 (87.0%)	46 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.100 (0.734, 50.708)
p-value			0.0561

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.4: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.6841
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	84 (54.2%)	57 (38.8%)	
Patients (%) Without Events (Censored)	71 (45.8%)	90 (61.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (1.0, NE)	9.6 (4.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.469 (1.049, 2.057)
p-value			0.0254
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	20 (43.5%)	18 (38.3%)	
Patients (%) Without Events (Censored)	26 (56.5%)	29 (61.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.251 (0.661, 2.366)
p-value			0.5007

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.4: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.4616
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	20 (12.9%)	8 (5.4%)	
Patients (%) Without Events (Censored)	135 (87.1%)	139 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.163 (0.950, 4.926)
p-value			0.0602
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	11 (23.9%)	3 (6.4%)	
Patients (%) Without Events (Censored)	35 (76.1%)	44 (93.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.945 (1.100, 14.148)
p-value			0.0231

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.4: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.7872
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	12 (7.7%)	2 (1.4%)	
Patients (%) Without Events (Censored)	143 (92.3%)	145 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.186 (1.157, 23.245)
p-value			0.0165
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	7 (15.2%)	1 (2.1%)	
Patients (%) Without Events (Censored)	39 (84.8%)	46 (97.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.785 (0.957, 63.300)
p-value			0.0230

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.4: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.4039
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	4 (2.6%)	11 (7.5%)	
Patients (%) Without Events (Censored)	151 (97.4%)	136 (92.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.253 (0.079, 0.804)
p-value			0.0122
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	3 (6.5%)	3 (6.4%)	
Patients (%) Without Events (Censored)	43 (93.5%)	44 (93.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.663 (0.111, 3.977)
p-value			0.6507

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.4: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Age group
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.4550
Age group: < 65 years			
Total Patients	155	147	
Patients (%) With Events	9 (5.8%)	15 (10.2%)	
Patients (%) Without Events (Censored)	146 (94.2%)	132 (89.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.451 (0.196, 1.038)
p-value			0.0550
Age group: >= 65 years			
Total Patients	46	47	
Patients (%) With Events	2 (4.3%)	2 (4.3%)	
Patients (%) Without Events (Censored)	44 (95.7%)	45 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.932 (0.130, 6.665)
p-value			0.9445

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.5: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.9897
Race: White			
Total Patients	141	132	
Patients (%) With Events	80 (56.7%)	58 (43.9%)	
Patients (%) Without Events (Censored)	61 (43.3%)	74 (56.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.9, 3.0)	6.0 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.401 (0.999, 1.965)
p-value			0.0513
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	7 (53.8%)	7 (43.8%)	
Patients (%) Without Events (Censored)	6 (46.2%)	9 (56.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.7 (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.401 (0.490, 4.009)
p-value			0.5673

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.5: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.9920
Race: White			
Total Patients	141	132	
Patients (%) With Events	13 (9.2%)	3 (2.3%)	
Patients (%) Without Events (Censored)	128 (90.8%)	129 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.651 (1.038, 12.844)
p-value			0.0309
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2827

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.5: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.9359
Race: White			
Total Patients	141	132	
Patients (%) With Events	75 (53.2%)	52 (39.4%)	
Patients (%) Without Events (Censored)	66 (46.8%)	80 (60.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (1.0, NE)	9.6 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.453 (1.020, 2.070)
p-value			0.0381
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	7 (53.8%)	7 (43.8%)	
Patients (%) Without Events (Censored)	6 (46.2%)	9 (56.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.7 (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.401 (0.490, 4.009)
p-value			0.5673

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.5: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.9884
Race: White			
Total Patients	141	132	
Patients (%) With Events	22 (15.6%)	9 (6.8%)	
Patients (%) Without Events (Censored)	119 (84.4%)	123 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.103 (0.966, 4.578)
p-value			0.0555
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	1 (6.3%)	
Patients (%) Without Events (Censored)	13 (100.0%)	15 (93.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.3674

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.5: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9997
Race: White			
Total Patients	141	132	
Patients (%) With Events	11 (7.8%)	2 (1.5%)	
Patients (%) Without Events (Censored)	130 (92.2%)	130 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.774 (1.055, 21.601)
p-value			0.0251
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.5: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.9997
Race: White			
Total Patients	141	132	
Patients (%) With Events	6 (4.3%)	13 (9.8%)	
Patients (%) Without Events (Censored)	135 (95.7%)	119 (90.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.258 (0.091, 0.732)
p-value			0.0062
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	0	0	
Patients (%) Without Events (Censored)	13 (100.0%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			NE

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.5: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Race
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.9898
Race: White			
Total Patients	141	132	
Patients (%) With Events	9 (6.4%)	12 (9.1%)	
Patients (%) Without Events (Censored)	132 (93.6%)	120 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.529 (0.221, 1.266)
p-value			0.1468
Race: Non-white			
Total Patients	13	16	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	16 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2994

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.6: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.8116
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	54 (62.1%)	39 (43.3%)	
Patients (%) Without Events (Censored)	33 (37.9%)	51 (56.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.7, 4.6)	8.3 (2.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.502 (0.994, 2.271)
p-value			0.0507
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	61 (53.5%)	44 (42.3%)	
Patients (%) Without Events (Censored)	53 (46.5%)	60 (57.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.9, NE)	NE (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.425 (0.967, 2.100)
p-value			0.0753

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.6: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.2964
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	7 (8.0%)	1 (1.1%)	
Patients (%) Without Events (Censored)	80 (92.0%)	89 (98.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.537 (0.803, 53.237)
p-value			0.0433
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	9 (7.9%)	4 (3.8%)	
Patients (%) Without Events (Censored)	105 (92.1%)	100 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.934 (0.595, 6.285)
p-value			0.2636

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.6: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.7893
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	49 (56.3%)	35 (38.9%)	
Patients (%) Without Events (Censored)	38 (43.7%)	55 (61.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.7 (0.9, NE)	8.3 (4.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.467 (0.950, 2.267)
p-value			0.0805
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	55 (48.2%)	40 (38.5%)	
Patients (%) Without Events (Censored)	59 (51.8%)	64 (61.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.0 (1.0, NE)	NE (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.386 (0.922, 2.083)
p-value			0.1228

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.6: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.8725
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	10 (11.5%)	4 (4.4%)	
Patients (%) Without Events (Censored)	77 (88.5%)	86 (95.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.473 (0.773, 7.909)
p-value			0.1149
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	21 (18.4%)	7 (6.7%)	
Patients (%) Without Events (Censored)	93 (81.6%)	97 (93.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.684 (1.140, 6.320)
p-value			0.0188

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.6: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.3885
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	7 (8.0%)	2 (2.2%)	
Patients (%) Without Events (Censored)	80 (92.0%)	88 (97.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.612 (0.750, 17.403)
p-value			0.0869
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	12 (10.5%)	1 (1.0%)	
Patients (%) Without Events (Censored)	102 (89.5%)	103 (99.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			10.500 (1.364, 80.844)
p-value			0.0049

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.6: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.4955
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	4 (4.6%)	5 (5.6%)	
Patients (%) Without Events (Censored)	83 (95.4%)	85 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.438 (0.103, 1.865)
p-value			0.2517
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	3 (2.6%)	9 (8.7%)	
Patients (%) Without Events (Censored)	111 (97.4%)	95 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.247 (0.067, 0.919)
p-value			0.0241

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.6: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline ECOG Status
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.2624
Screening ECOG Status: 0			
Total Patients	87	90	
Patients (%) With Events	2 (2.3%)	7 (7.8%)	
Patients (%) Without Events (Censored)	85 (97.7%)	83 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.253 (0.052, 1.226)
p-value			0.0656
Screening ECOG Status: 1			
Total Patients	114	104	
Patients (%) With Events	9 (7.9%)	10 (9.6%)	
Patients (%) Without Events (Censored)	105 (92.1%)	94 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.665 (0.268, 1.645)
p-value			0.3750

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.7: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.0365
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	65 (52.8%)	57 (47.1%)	
Patients (%) Without Events (Censored)	58 (47.2%)	64 (52.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (1.0, NE)	6.0 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.151 (0.806, 1.643)
p-value			0.4307
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	50 (64.1%)	26 (35.6%)	
Patients (%) Without Events (Censored)	28 (35.9%)	47 (64.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.9 (0.5, 2.6)	NE (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.161 (1.344, 3.475)
p-value			0.0013

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.7: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.6104
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	8 (6.5%)	2 (1.7%)	
Patients (%) Without Events (Censored)	115 (93.5%)	119 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.661 (0.775, 17.281)
p-value			0.0793
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	8 (10.3%)	3 (4.1%)	
Patients (%) Without Events (Censored)	70 (89.7%)	70 (95.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.156 (0.571, 8.146)
p-value			0.2464

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.7: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.0039
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	56 (45.5%)	54 (44.6%)	
Patients (%) Without Events (Censored)	67 (54.5%)	67 (55.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.4, NE)	8.3 (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.011 (0.695, 1.470)
p-value			0.9519
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	48 (61.5%)	21 (28.8%)	
Patients (%) Without Events (Censored)	30 (38.5%)	52 (71.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.5, 3.0)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.564 (1.534, 4.285)
p-value			0.0002

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.7: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.0175
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	21 (17.1%)	3 (2.5%)	
Patients (%) Without Events (Censored)	102 (82.9%)	118 (97.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.786 (2.021, 22.786)
p-value			0.0003
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	10 (12.8%)	8 (11.0%)	
Patients (%) Without Events (Censored)	68 (87.2%)	65 (89.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.090 (0.430, 2.765)
p-value			0.8552

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.7: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.3090
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	12 (9.8%)	1 (0.8%)	
Patients (%) Without Events (Censored)	111 (90.2%)	120 (99.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			11.458 (1.488, 88.251)
p-value			0.0031
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	7 (9.0%)	2 (2.7%)	
Patients (%) Without Events (Censored)	71 (91.0%)	71 (97.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.138 (0.651, 15.131)
p-value			0.1332

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.7: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.5830
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	4 (3.3%)	8 (6.6%)	
Patients (%) Without Events (Censored)	119 (96.7%)	113 (93.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.383 (0.114, 1.281)
p-value			0.1060
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	3 (3.8%)	6 (8.2%)	
Patients (%) Without Events (Censored)	75 (96.2%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.241 (0.048, 1.202)
p-value			0.0599

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.7: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.8982
Geographic Region: Europe			
Total Patients	123	121	
Patients (%) With Events	7 (5.7%)	11 (9.1%)	
Patients (%) Without Events (Censored)	116 (94.3%)	110 (90.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.545 (0.210, 1.413)
p-value			0.2054
Geographic Region: North America			
Total Patients	78	73	
Patients (%) With Events	4 (5.1%)	6 (8.2%)	
Patients (%) Without Events (Censored)	74 (94.9%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.447 (0.125, 1.603)
p-value			0.2057

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.8: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.6654
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	65 (56.0%)	50 (42.0%)	
Patients (%) Without Events (Censored)	51 (44.0%)	69 (58.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (1.0, 4.6)	8.3 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.368 (0.945, 1.979)
p-value			0.0878
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	48 (60.0%)	33 (45.2%)	
Patients (%) Without Events (Censored)	32 (40.0%)	40 (54.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.7, NE)	6.0 (1.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.583 (1.016, 2.468)
p-value			0.0474

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.8: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.3678
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	9 (7.8%)	4 (3.4%)	
Patients (%) Without Events (Censored)	107 (92.2%)	115 (96.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.944 (0.595, 6.359)
p-value			0.2632
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	7 (8.8%)	1 (1.4%)	
Patients (%) Without Events (Censored)	73 (91.3%)	72 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.153 (0.757, 50.019)
p-value			0.0521

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.8: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.4841
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	57 (49.1%)	45 (37.8%)	
Patients (%) Without Events (Censored)	59 (50.9%)	74 (62.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.8 (1.2, NE)	9.6 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.286 (0.870, 1.903)
p-value			0.1965
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	45 (56.3%)	30 (41.1%)	
Patients (%) Without Events (Censored)	35 (43.8%)	43 (58.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.7, NE)	NE (2.8, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.625 (1.023, 2.580)
p-value			0.0434

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.8: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.6436
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	19 (16.4%)	6 (5.0%)	
Patients (%) Without Events (Censored)	97 (83.6%)	113 (95.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.094 (1.231, 7.772)
p-value			0.0115
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	12 (15.0%)	5 (6.8%)	
Patients (%) Without Events (Censored)	68 (85.0%)	68 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.168 (0.764, 6.153)
p-value			0.1364

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.8: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9673
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	12 (10.3%)	2 (1.7%)	
Patients (%) Without Events (Censored)	104 (89.7%)	117 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.165 (1.379, 27.567)
p-value			0.0065
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	7 (8.8%)	1 (1.4%)	
Patients (%) Without Events (Censored)	73 (91.3%)	72 (98.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			6.142 (0.756, 49.935)
p-value			0.0524

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.8: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.8868
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	3 (2.6%)	7 (5.9%)	
Patients (%) Without Events (Censored)	113 (97.4%)	112 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.263 (0.066, 1.049)
p-value			0.0437
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	4 (5.0%)	7 (9.6%)	
Patients (%) Without Events (Censored)	76 (95.0%)	66 (90.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.357 (0.092, 1.381)
p-value			0.1188

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.8: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Prior CDK Treatment Duration
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.5964
Prior CDK treatment duration: <= 12 months			
Total Patients	116	119	
Patients (%) With Events	6 (5.2%)	11 (9.2%)	
Patients (%) Without Events (Censored)	110 (94.8%)	108 (90.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.451 (0.165, 1.228)
p-value			0.1102
Prior CDK treatment duration: > 12 months			
Total Patients	80	73	
Patients (%) With Events	5 (6.3%)	6 (8.2%)	
Patients (%) Without Events (Censored)	75 (93.8%)	67 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.661 (0.201, 2.169)
p-value			0.4912

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.9: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.9096
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	7 (53.8%)	5 (35.7%)	
Patients (%) Without Events (Censored)	6 (46.2%)	9 (64.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.567 (0.497, 4.943)
p-value			0.4416
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	104 (57.5%)	77 (43.8%)	
Patients (%) Without Events (Censored)	77 (42.5%)	99 (56.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.2 (0.9, 3.0)	8.3 (2.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.430 (1.064, 1.920)
p-value			0.0171

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.9: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.9930
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.3, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.6547
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	15 (8.3%)	5 (2.8%)	
Patients (%) Without Events (Censored)	166 (91.7%)	171 (97.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.747 (0.997, 7.569)
p-value			0.0416

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.9: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.8366
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	6 (46.2%)	4 (28.6%)	
Patients (%) Without Events (Censored)	7 (53.8%)	10 (71.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (0.3, NE)	NE (0.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.695 (0.478, 6.013)
p-value			0.4124
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	95 (52.5%)	70 (39.8%)	
Patients (%) Without Events (Censored)	86 (47.5%)	106 (60.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (1.0, NE)	9.6 (4.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.410 (1.035, 1.921)
p-value			0.0293

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.9: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.3890
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	1 (7.1%)	
Patients (%) Without Events (Censored)	12 (92.3%)	13 (92.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.411 (0.021, 7.892)
p-value			0.5467
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	29 (16.0%)	10 (5.7%)	
Patients (%) Without Events (Censored)	152 (84.0%)	166 (94.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.777 (1.352, 5.703)
p-value			0.0037

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.9: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9901
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	0	
Patients (%) Without Events (Censored)	12 (92.3%)	14 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (3.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.6547
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	17 (9.4%)	3 (1.7%)	
Patients (%) Without Events (Censored)	164 (90.6%)	173 (98.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			5.479 (1.604, 18.711)
p-value			0.0023

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.9: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.7279
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	2 (14.3%)	
Patients (%) Without Events (Censored)	12 (92.3%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (6.5, NE)	4.6 (4.6, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0309
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	6 (3.3%)	12 (6.8%)	
Patients (%) Without Events (Censored)	175 (96.7%)	164 (93.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.331 (0.116, 0.945)
p-value			0.0301

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.9: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Early Relapse
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.6103
Early relapse: Yes			
Total Patients	13	14	
Patients (%) With Events	1 (7.7%)	2 (14.3%)	
Patients (%) Without Events (Censored)	12 (92.3%)	12 (85.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.487 (0.044, 5.370)
p-value			0.5481
Early relapse: No			
Total Patients	181	176	
Patients (%) With Events	10 (5.5%)	15 (8.5%)	
Patients (%) Without Events (Censored)	171 (94.5%)	161 (91.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.535 (0.239, 1.194)
p-value			0.1212

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.10: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.8768
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	103 (58.2%)	75 (43.9%)	
Patients (%) Without Events (Censored)	74 (41.8%)	96 (56.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.1 (0.9, 2.6)	8.3 (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.449 (1.075, 1.952)
p-value			0.0142
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	12 (50.0%)	8 (34.8%)	
Patients (%) Without Events (Censored)	12 (50.0%)	15 (65.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.7 (0.6, NE)	NE (0.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.586 (0.648, 3.886)
p-value			0.3198

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.10: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.3552
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	15 (8.5%)	4 (2.3%)	
Patients (%) Without Events (Censored)	162 (91.5%)	167 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.360 (1.113, 10.142)
p-value			0.0224
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	1 (4.2%)	1 (4.3%)	
Patients (%) Without Events (Censored)	23 (95.8%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.789 (0.049, 12.784)
p-value			0.8674

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.10: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.9642
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	94 (53.1%)	68 (39.8%)	
Patients (%) Without Events (Censored)	83 (46.9%)	103 (60.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (1.0, 6.9)	9.6 (4.3, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.424 (1.042, 1.947)
p-value			0.0259
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	10 (41.7%)	7 (30.4%)	
Patients (%) Without Events (Censored)	14 (58.3%)	16 (69.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (1.0, NE)	NE (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.489 (0.566, 3.916)
p-value			0.4313

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.10: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.4705
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	25 (14.1%)	10 (5.8%)	
Patients (%) Without Events (Censored)	152 (85.9%)	161 (94.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.336 (1.120, 4.872)
p-value			0.0200
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	6 (25.0%)	1 (4.3%)	
Patients (%) Without Events (Censored)	18 (75.0%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			4.656 (0.559, 38.799)
p-value			0.1177

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.10: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.5787
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	15 (8.5%)	2 (1.2%)	
Patients (%) Without Events (Censored)	162 (91.5%)	169 (98.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			7.182 (1.640, 31.441)
p-value			0.0022
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	4 (16.7%)	1 (4.3%)	
Patients (%) Without Events (Censored)	20 (83.3%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.844 (0.316, 25.570)
p-value			0.3294

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.10: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.5723
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	6 (3.4%)	13 (7.6%)	
Patients (%) Without Events (Censored)	171 (96.6%)	158 (92.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.294 (0.104, 0.830)
p-value			0.0141
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	1 (4.2%)	1 (4.3%)	
Patients (%) Without Events (Censored)	23 (95.8%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.674 (0.042, 10.779)
p-value			0.7790

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.10: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Baseline Documented Tartget vs Non-Target Liver Lesions
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.2967
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): Yes			
Total Patients	177	171	
Patients (%) With Events	7 (4.0%)	14 (8.2%)	
Patients (%) Without Events (Censored)	170 (96.0%)	157 (91.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.405 (0.163, 1.008)
p-value			0.0448
Baseline documented Target or Non-target liver lesions per RECIST1.1 per Local Investigator Review (LIR): No			
Total Patients	24	23	
Patients (%) With Events	4 (16.7%)	3 (13.0%)	
Patients (%) Without Events (Censored)	20 (83.3%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (7.6, NE)	NE (7.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.003 (0.222, 4.536)
p-value			0.9965

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.11: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.6235
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	67 (54.9%)	51 (39.5%)	
Patients (%) Without Events (Censored)	55 (45.1%)	78 (60.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.9, 6.9)	NE (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.535 (1.066, 2.211)
p-value			0.0205
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	48 (60.8%)	32 (49.2%)	
Patients (%) Without Events (Censored)	31 (39.2%)	33 (50.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.7, 3.5)	8.3 (1.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.308 (0.836, 2.047)
p-value			0.2413

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.11: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.1597
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	6 (4.9%)	4 (3.1%)	
Patients (%) Without Events (Censored)	116 (95.1%)	125 (96.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.383 (0.389, 4.916)
p-value			0.6149
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	10 (12.7%)	1 (1.5%)	
Patients (%) Without Events (Censored)	69 (87.3%)	64 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			8.073 (1.032, 63.138)
p-value			0.0178

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.11: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.7271
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	59 (48.4%)	45 (34.9%)	
Patients (%) Without Events (Censored)	63 (51.6%)	84 (65.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	4.6 (1.0, NE)	NE (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.476 (1.001, 2.176)
p-value			0.0485
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	45 (57.0%)	30 (46.2%)	
Patients (%) Without Events (Censored)	34 (43.0%)	35 (53.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.9, NE)	8.3 (1.9, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.319 (0.830, 2.094)
p-value			0.2452

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.11: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.1403
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	19 (15.6%)	10 (7.8%)	
Patients (%) Without Events (Censored)	103 (84.4%)	119 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.898 (0.880, 4.090)
p-value			0.0971
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	12 (15.2%)	1 (1.5%)	
Patients (%) Without Events (Censored)	67 (84.8%)	64 (98.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			9.778 (1.271, 75.255)
p-value			0.0071

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.11: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.9892
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	11 (9.0%)	3 (2.3%)	
Patients (%) Without Events (Censored)	111 (91.0%)	126 (97.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.593 (0.999, 12.925)
p-value			0.0365
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	8 (10.1%)	0	
Patients (%) Without Events (Censored)	71 (89.9%)	65 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0097

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

Data Extracted: 28FEB2022, Data Cut Date 1 (PFS FA/OS IA1): 03JAN2022. Data Extracted: 09AUG2022, Data Cut Date 2 (SUR/OS IA2): 01JUL2022
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Table 15.11.7.4.11: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.8971
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	4 (3.3%)	7 (5.4%)	
Patients (%) Without Events (Censored)	118 (96.7%)	122 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.301 (0.077, 1.177)
p-value			0.0680
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	3 (3.8%)	7 (10.8%)	
Patients (%) Without Events (Censored)	76 (96.2%)	58 (89.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.313 (0.081, 1.216)
p-value			0.0764

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.11: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Chemotherapy in Neo/adjuvant Setting
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.5140
Chemotherapy in neo/adjuvant setting: Yes			
Total Patients	122	129	
Patients (%) With Events	8 (6.6%)	11 (8.5%)	
Patients (%) Without Events (Censored)	114 (93.4%)	118 (91.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.585 (0.233, 1.468)
p-value			0.2486
Chemotherapy in neo/adjuvant setting: No			
Total Patients	79	65	
Patients (%) With Events	3 (3.8%)	6 (9.2%)	
Patients (%) Without Events (Censored)	76 (96.2%)	59 (90.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.370 (0.092, 1.483)
p-value			0.1442

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.4078
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	40 (58.8%)	37 (51.4%)	
Patients (%) Without Events (Censored)	28 (41.2%)	35 (48.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.6 (0.7, 4.6)	2.5 (1.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.262 (0.806, 1.974)
p-value			0.3214
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	37 (52.1%)	27 (36.5%)	
Patients (%) Without Events (Censored)	34 (47.9%)	47 (63.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.0 (0.9, NE)	8.3 (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.374 (0.834, 2.262)
p-value			0.2089
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	25 (62.5%)	12 (46.2%)	
Patients (%) Without Events (Censored)	15 (37.5%)	14 (53.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	0.8 (0.5, 2.6)	9.6 (2.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.732 (0.869, 3.452)
p-value			0.1149

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.2943
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	37 (54.4%)	35 (48.6%)	
Patients (%) Without Events (Censored)	31 (45.6%)	37 (51.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.3 (0.7, 4.8)	4.4 (1.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.222 (0.769, 1.940)
p-value			0.4116
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	33 (46.5%)	24 (32.4%)	
Patients (%) Without Events (Censored)	38 (53.5%)	50 (67.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	6.9 (1.2, NE)	8.3 (6.0, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.346 (0.793, 2.284)
p-value			0.2675
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	21 (52.5%)	9 (34.6%)	
Patients (%) Without Events (Censored)	19 (47.5%)	17 (65.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.5, NE)	9.6 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.912 (0.874, 4.182)
p-value			0.1016

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.6215
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	12 (17.6%)	5 (6.9%)	
Patients (%) Without Events (Censored)	56 (82.4%)	67 (93.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.648 (0.933, 7.520)
p-value			0.0585
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	14 (19.7%)	4 (5.4%)	
Patients (%) Without Events (Censored)	57 (80.3%)	70 (94.6%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (10.4, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.972 (0.964, 9.162)
p-value			0.0471
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	2 (5.0%)	1 (3.8%)	
Patients (%) Without Events (Censored)	38 (95.0%)	25 (96.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.359 (0.123, 14.996)
p-value			0.8014

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.1594
Trop2: H-Score < 100			
Total Patients	68	72	
Patients (%) With Events	5 (7.4%)	4 (5.6%)	
Patients (%) Without Events (Censored)	63 (92.6%)	68 (94.4%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.288 (0.345, 4.803)
p-value			0.7053
Trop2: H-Score >= 100 and <= 200			
Total Patients	71	74	
Patients (%) With Events	3 (4.2%)	9 (12.2%)	
Patients (%) Without Events (Censored)	68 (95.8%)	65 (87.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.256 (0.068, 0.969)
p-value			0.0318
Trop2: H-Score > 200			
Total Patients	40	26	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.12: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Trop2 H-Score
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	1 (2.5%)	3 (11.5%)	
Patients (%) Without Events (Censored)	39 (97.5%)	23 (88.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.205 (0.021, 1.969)
p-value			0.1281

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Blood and lymphatic system disorders			
Interaction p-value			0.0055
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	13 (61.9%)	1 (4.3%)	
Patients (%) Without Events (Censored)	8 (38.1%)	22 (95.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			19.794 (2.582, 151.777)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	71 (56.3%)	55 (45.8%)	
Patients (%) Without Events (Censored)	55 (43.7%)	65 (54.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.3 (0.7, 4.6)	6.0 (2.5, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.332 (0.936, 1.897)
p-value			0.1032
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	31 (57.4%)	27 (52.9%)	
Patients (%) Without Events (Censored)	23 (42.6%)	24 (47.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.0 (0.9, NE)	1.4 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.987 (0.585, 1.666)
p-value			0.9389

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Anaemia			
Interaction p-value			0.9897
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	0	
Patients (%) Without Events (Censored)	19 (90.5%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1437
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	9 (7.1%)	4 (3.3%)	
Patients (%) Without Events (Censored)	117 (92.9%)	116 (96.7%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.128 (0.655, 6.912)
p-value			0.1978
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	5 (9.3%)	1 (2.0%)	
Patients (%) Without Events (Censored)	49 (90.7%)	50 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.767 (0.427, 33.200)
p-value			0.2010

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Neutropenia			
Interaction p-value			0.9753
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	13 (61.9%)	0	
Patients (%) Without Events (Censored)	8 (38.1%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	2.6 (0.7, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			<0.0001
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	63 (50.0%)	51 (42.5%)	
Patients (%) Without Events (Censored)	63 (50.0%)	69 (57.5%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	3.7 (1.1, NE)	8.3 (3.1, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.236 (0.854, 1.789)
p-value			0.2531
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	28 (51.9%)	24 (47.1%)	
Patients (%) Without Events (Censored)	26 (48.1%)	27 (52.9%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	1.9 (0.9, NE)	2.4 (0.7, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.068 (0.616, 1.853)
p-value			0.8397

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Gastrointestinal disorders			
Interaction p-value			0.8730
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	5 (23.8%)	3 (13.0%)	
Patients (%) Without Events (Censored)	16 (76.2%)	20 (87.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (5.2, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.932 (0.461, 8.088)
p-value			0.3557
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	20 (15.9%)	6 (5.0%)	
Patients (%) Without Events (Censored)	106 (84.1%)	114 (95.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			3.239 (1.300, 8.070)
p-value			0.0076
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	6 (11.1%)	2 (3.9%)	
Patients (%) Without Events (Censored)	48 (88.9%)	49 (96.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.814 (0.355, 9.274)
p-value			0.4686

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE - Diarrhoea			
Interaction p-value			0.6621
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	2 (9.5%)	2 (8.7%)	
Patients (%) Without Events (Censored)	19 (90.5%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			1.121 (0.158, 7.963)
p-value			0.9089
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	14 (11.1%)	0	
Patients (%) Without Events (Censored)	112 (88.9%)	120 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0002
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (5.6%)	1 (2.0%)	
Patients (%) Without Events (Censored)	51 (94.4%)	50 (98.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			2.303 (0.237, 22.397)
p-value			0.4599

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Nervous system disorders			
Interaction p-value			0.9928
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	1 (4.8%)	0	
Patients (%) Without Events (Censored)	20 (95.2%)	23 (100.0%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.2953
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	6 (4.8%)	11 (9.2%)	
Patients (%) Without Events (Censored)	120 (95.2%)	109 (90.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	29.7 (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.370 (0.128, 1.069)
p-value			0.0557
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	0	3 (5.9%)	
Patients (%) Without Events (Censored)	54 (100.0%)	48 (94.1%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.0127

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Frequent TEAE SOC - Respiratory, thoracic and mediastinal disorders			
Interaction p-value			0.9885
Investigators' Choice of Chemotherapy: Capecitabine			
Total Patients	21	23	
Patients (%) With Events	0	2 (8.7%)	
Patients (%) Without Events (Censored)	21 (100.0%)	21 (91.3%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (7.4, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			NE (NE, NE)
p-value			0.1470
Investigators' Choice of Chemotherapy: Eribulin			
Total Patients	126	120	
Patients (%) With Events	8 (6.3%)	11 (9.2%)	
Patients (%) Without Events (Censored)	118 (93.7%)	109 (90.8%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.623 (0.250, 1.553)
p-value			0.3060
Investigators' Choice of Chemotherapy: Vinorelbine			
Total Patients	54	51	

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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Table 15.11.7.4.13: Time to the First Grade 3 or Higher Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

	SG (N=201)	TPC (N=194)	Treatment Comparison
Patients (%) With Events	3 (5.6%)	4 (7.8%)	
Patients (%) Without Events (Censored)	51 (94.4%)	47 (92.2%)	
Kaplan-Meier Quartiles of Time to Event (months)			
Median (95% CI)	NE (NE, NE)	NE (NE, NE)	
Analysis SG vs. TPC			
Hazard Ratio (95% CI)			0.495 (0.108, 2.270)
p-value			0.3565

The denominator is the number of patients in the Safety Population excluding pre-selected to Gemcitabine for each treatment group per subgroup.
The SOC/PT is kept if the number of patients of is no less than 10 or the incidence is no less than 5% in at least one treatment arm.
Stratified log rank test is performed for treatment comparison in each SOC/PT, which is only be kept when the test is significant.
The SOC/PT in the subgroup will be kept if at least one category of the subgroup has no less than 10 patients with events in total (SG + TPC).
Interaction p-value is from Cox regression with treatment, subgroup and treatment*subgroup interaction as covariates.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.
Median event time is from Kaplan-Meier estimate and its 95% CI is from Brookmeyer-Crowley method. NE = Not Estimable.

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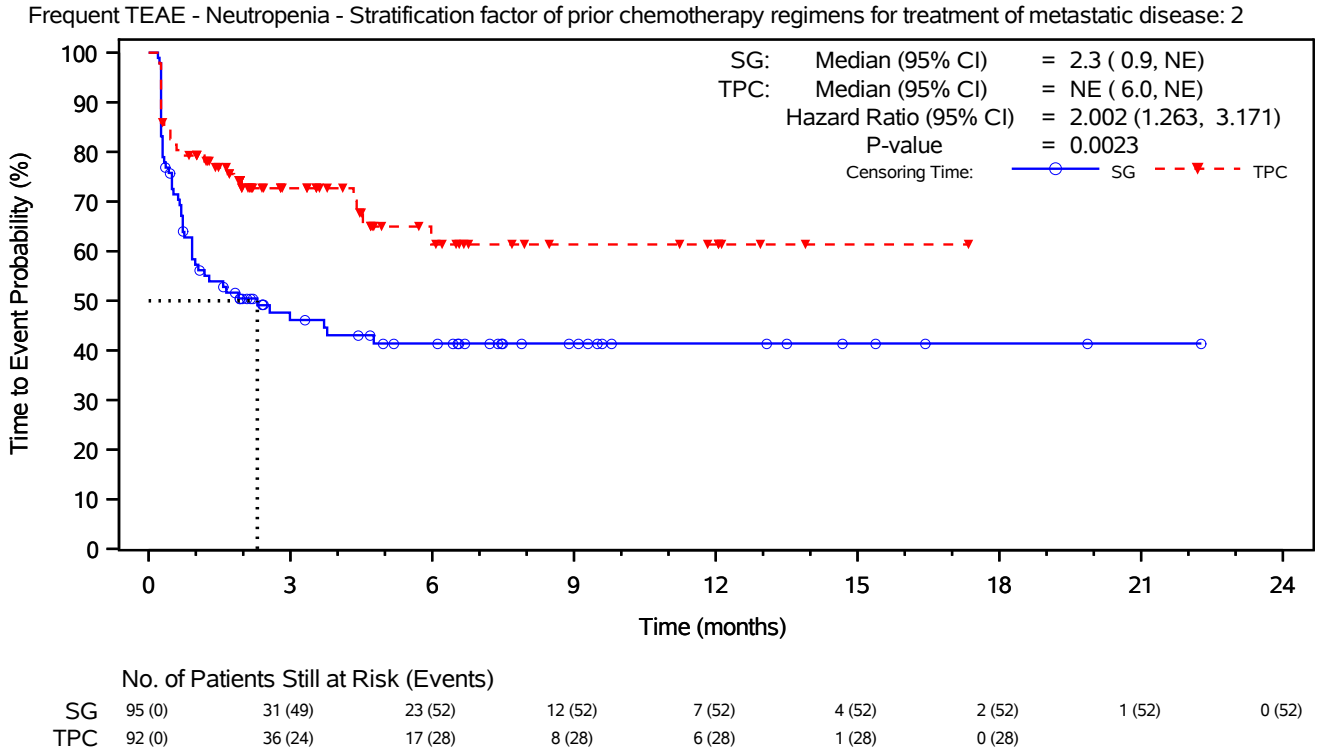
Figure 15.11.7.4.1: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine



The analysis is based on Interim 2 data cut at 01Jul2022.
NE = not estimable.
Hazard ratios and CIs are from an unstratified Cox regression analysis. P-values are from an unstratified log-rank test.

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Figure 15.11.7.4.1: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Prior Chemotherapy for Treatment of Metastatic Disease
Safety Population
Excluding participants pre-selected to Gemcitabine

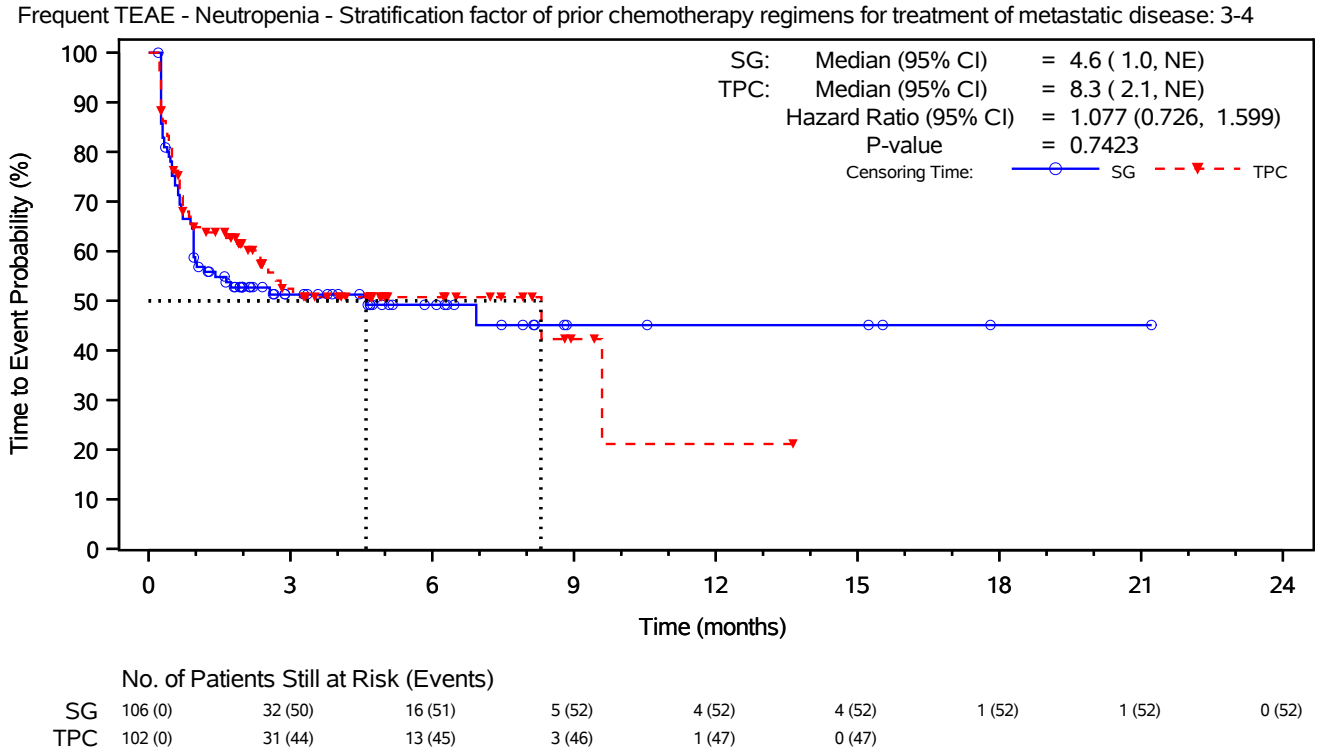

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Figure 15.11.7.4.2: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

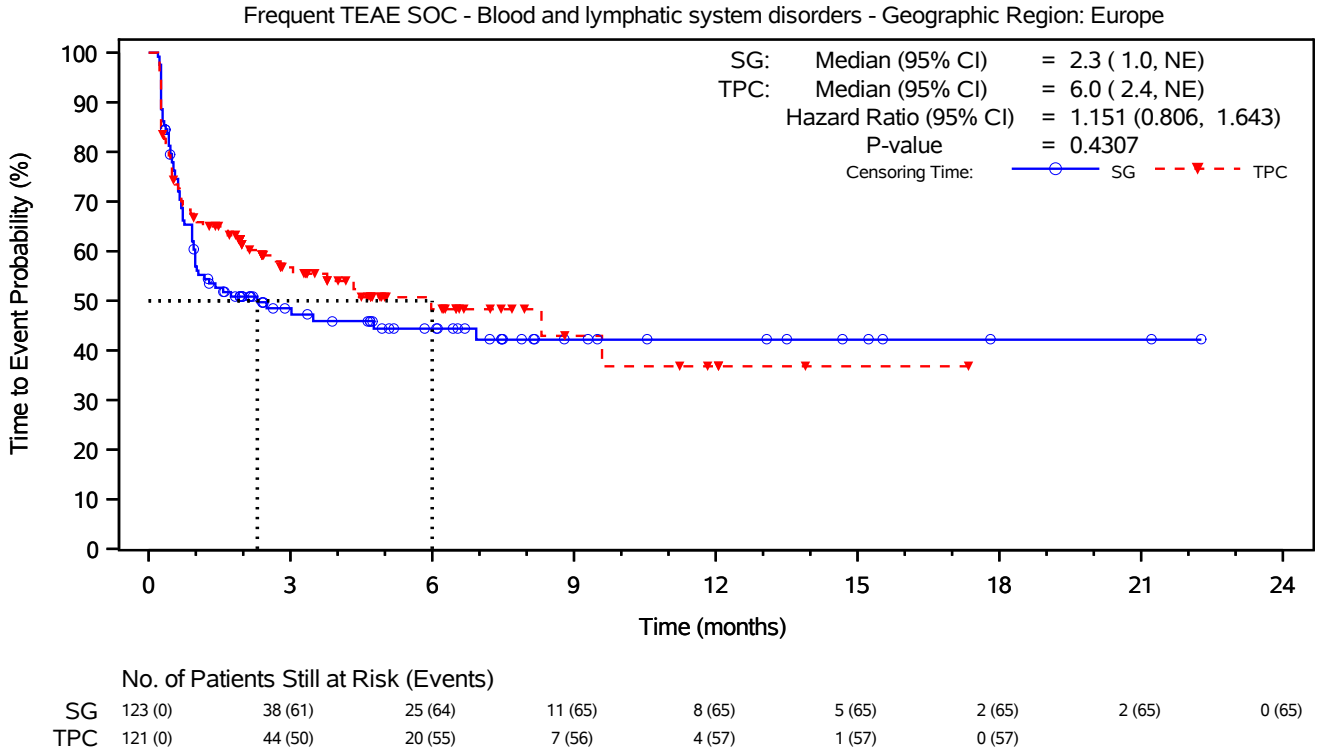

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Figure 15.11.7.4.2: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

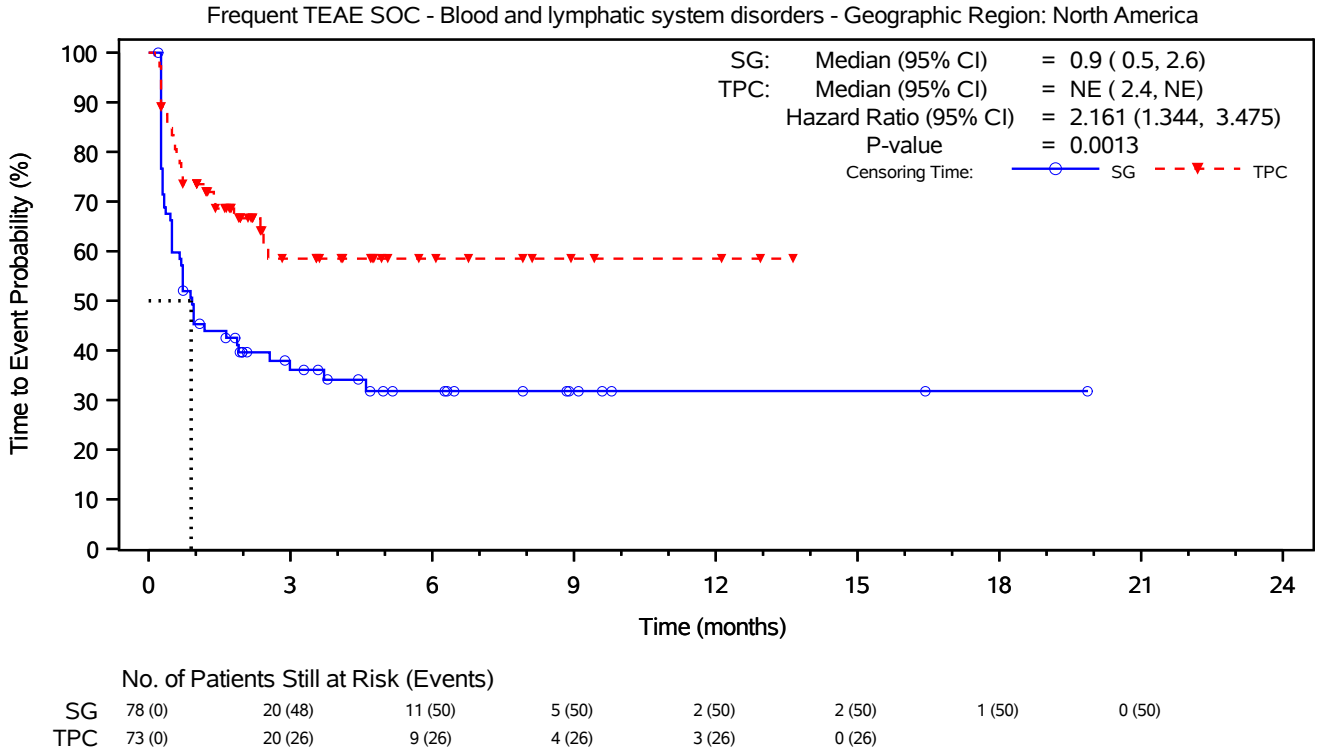

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Figure 15.11.7.4.2: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

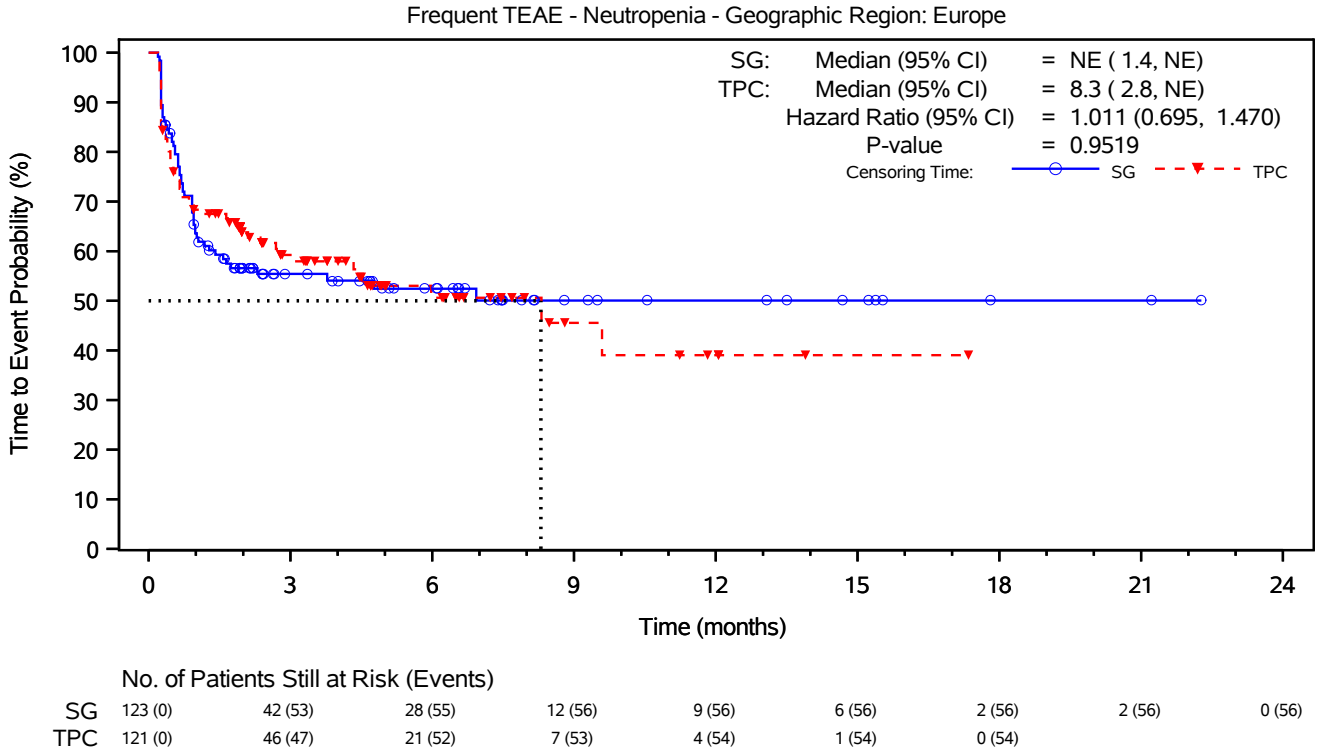

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Figure 15.11.7.4.2: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

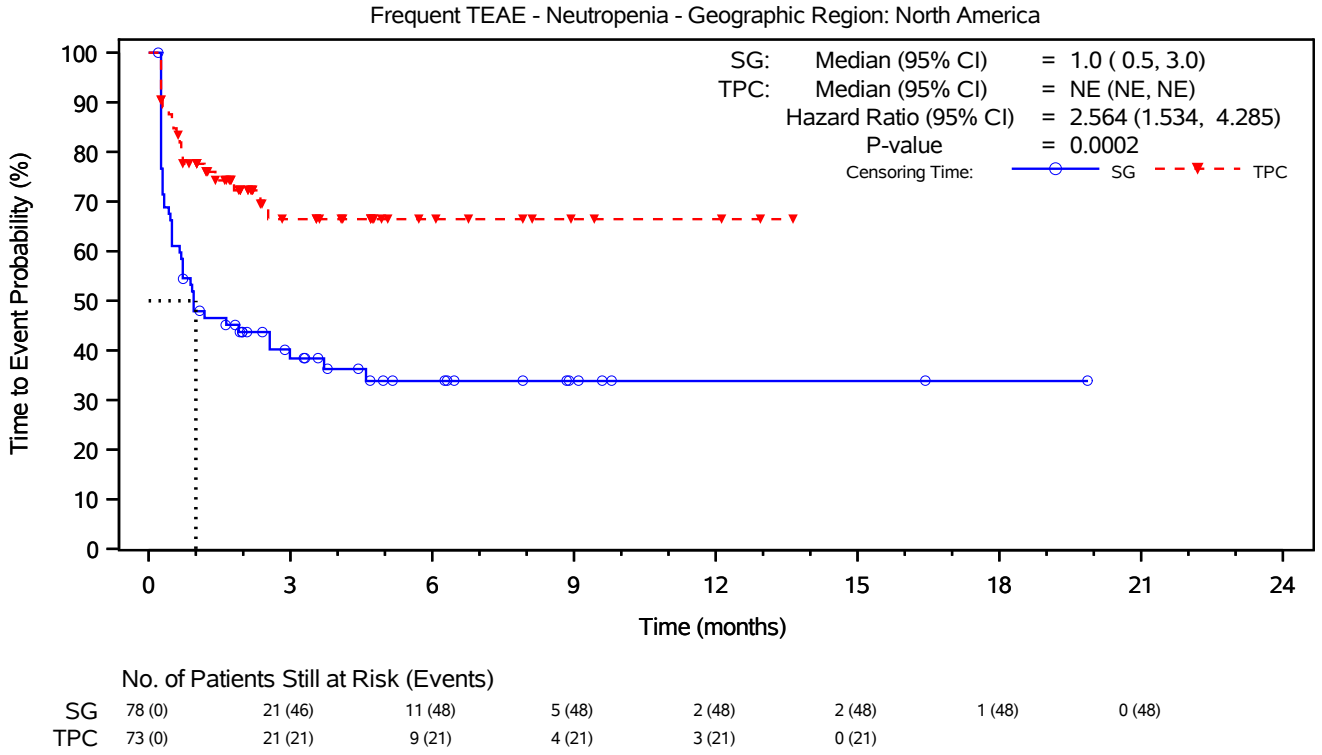

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Figure 15.11.7.4.2: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

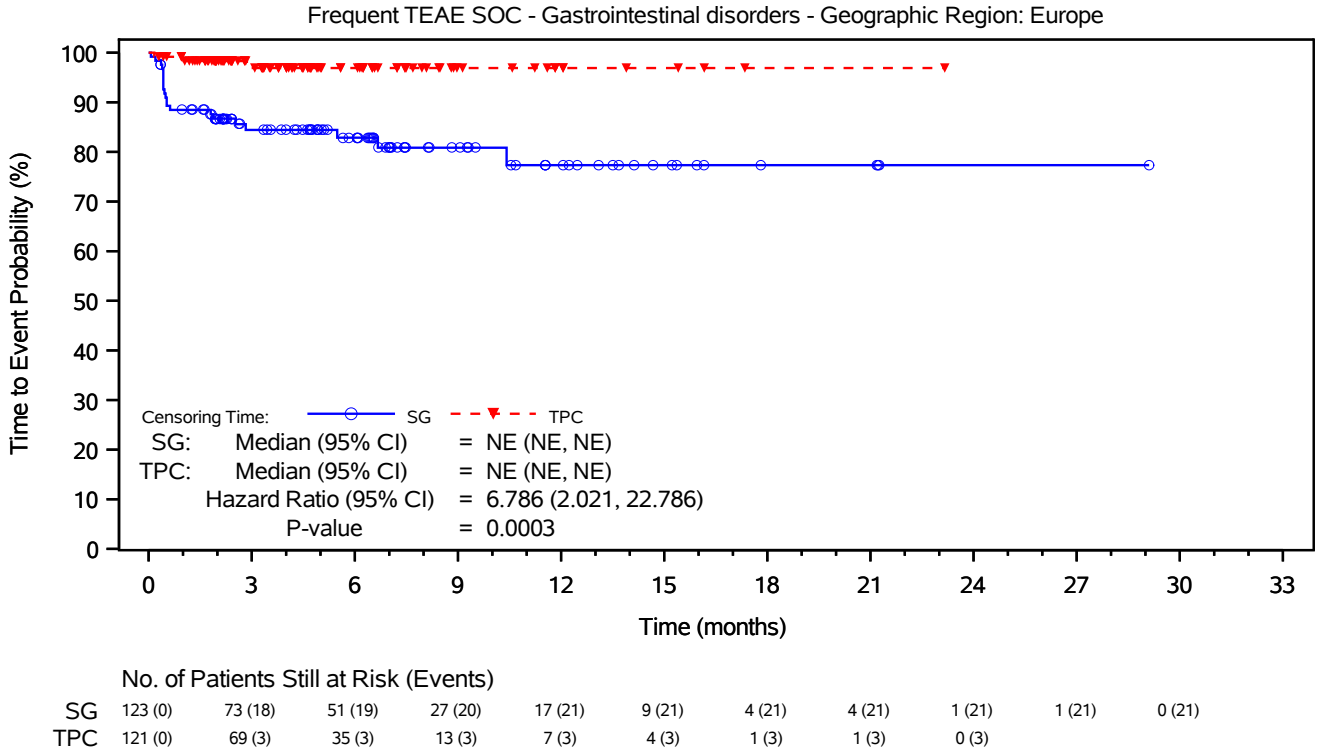

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Figure 15.11.7.4.2: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Geographic Region
Safety Population
Excluding participants pre-selected to Gemcitabine

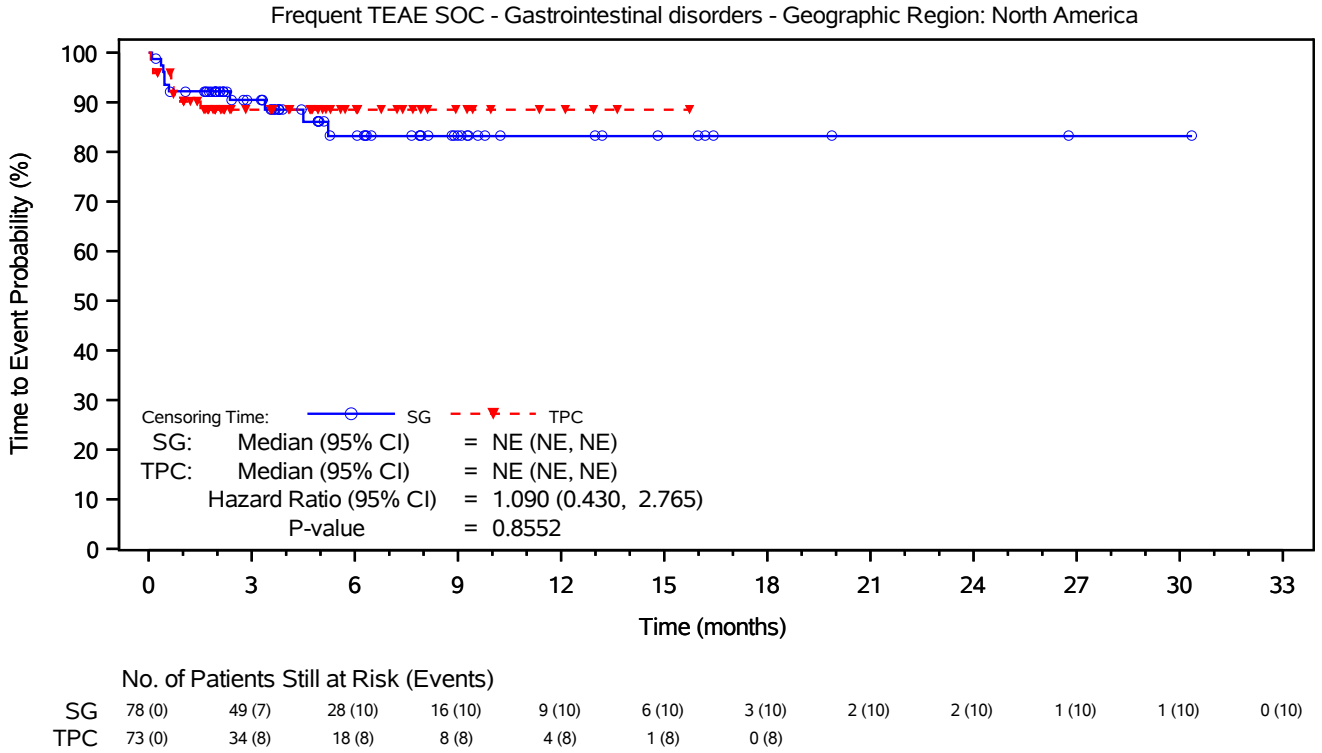

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Figure 15.11.7.4.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

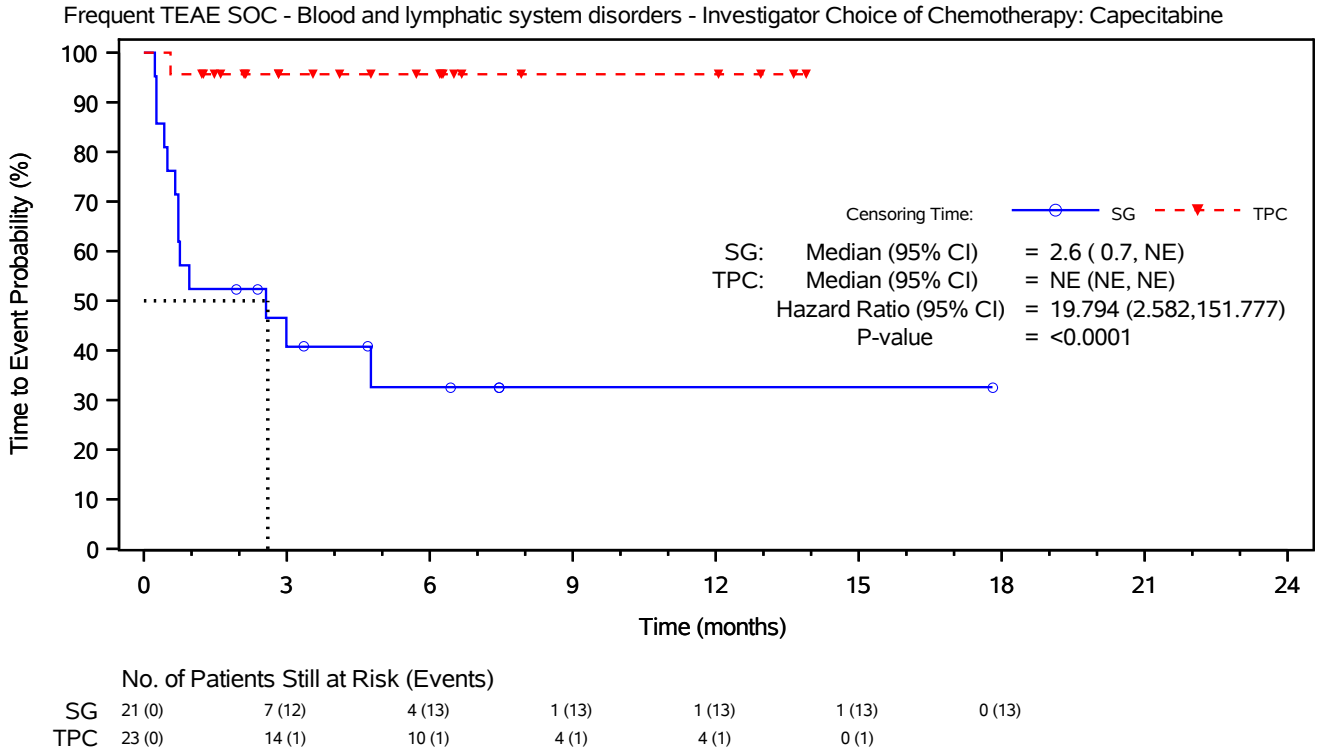

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Figure 15.11.7.4.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine

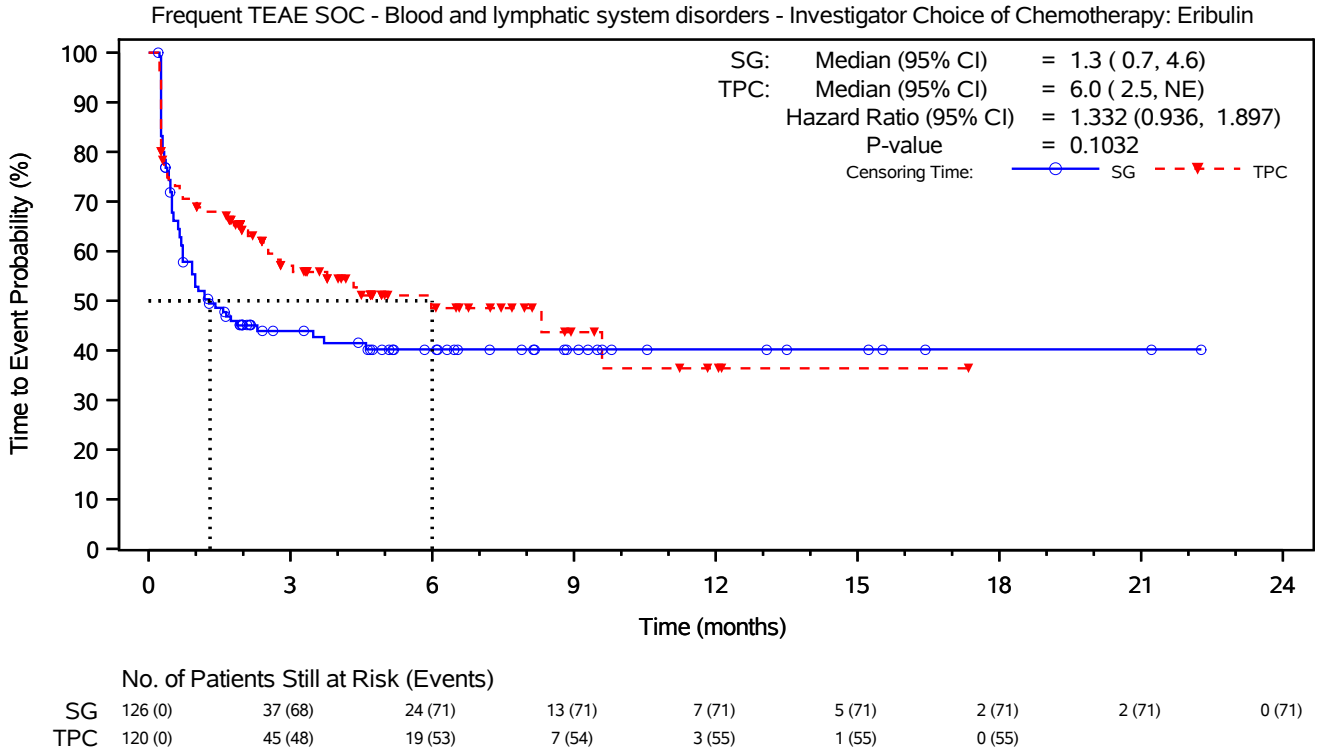

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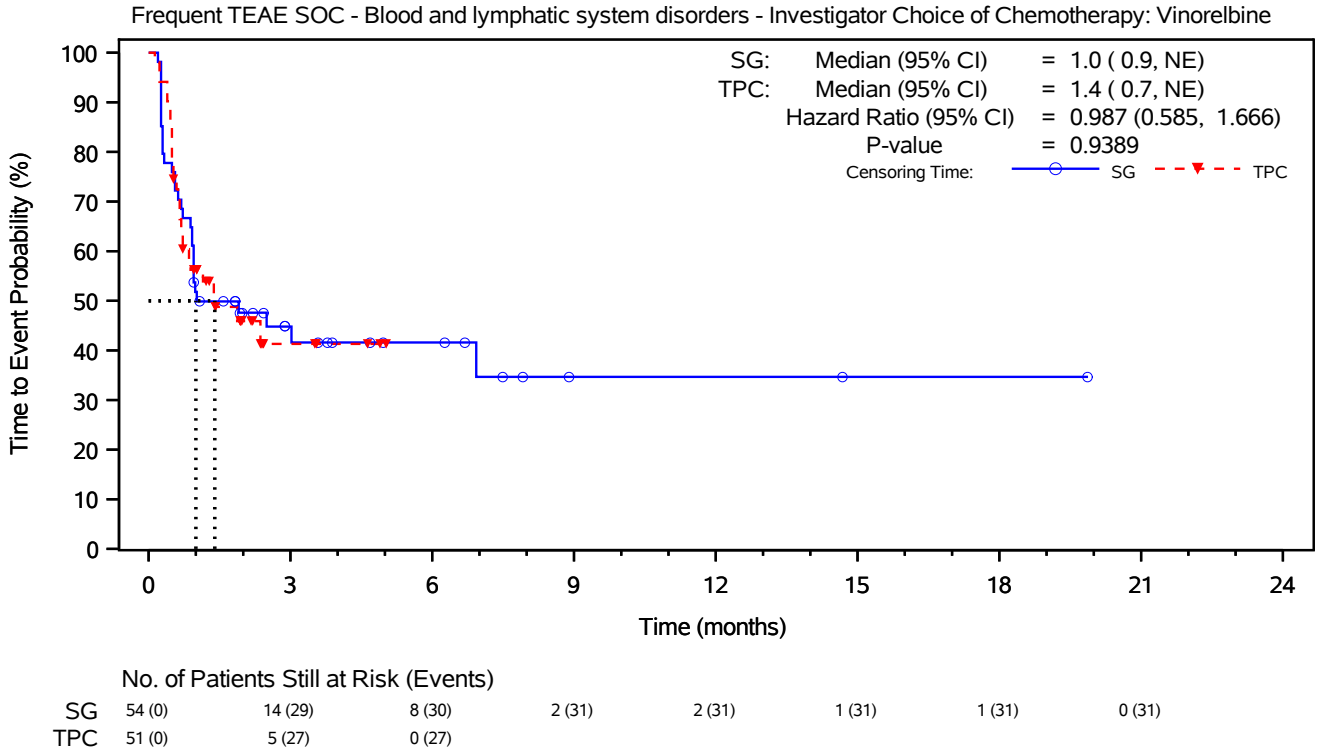
Figure 15.11.7.4.3: KM Plot for Time to the First >=Grade 3 Frequent TEAE by SOC, PT and Investigator Choice of Chemotherapy Prior to Randomization
Safety Population
Excluding participants pre-selected to Gemcitabine



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